Medical technology guidance

Assessment report overview

The Memokath-051 stent for the treatment of ureteric obstruction

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes brief descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company submission of evidence and with the EAC assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This report contains no confidential information. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: Claimed benefits and decision problem from scope
1 The technology

The Memokath-051 is a thermo-expandable, nickel-titanium shape memory alloy ureteric stent. The indication for this technology is as an alternative to conventional ureteric stents for people with ureteric obstruction as a result of benign or malignant strictures. The thermo-expandable alloy allows the stent to be more easily inserted and anchored in 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 Memokath-051 are available: either single or double cone design; for each design there are 2 versions for either antegrade or retrograde insertion, and each version is available in a variety of lengths. The use of other Memokath stents used for treating obstruction elsewhere in the urinary tract, are not considered in this evaluation.

2 Proposed use of the technology

2.1 Disease or condition

Ureteric stricture is characterised by a narrowing of the ureter and can have malignant or benign causes. When the ureter is obstructed, the normal flow of urine from the kidney to the bladder is disrupted which can lead to pressure build-up in the kidneys and acute kidney injury, which may lead to chronic kidney disease. People with ureteric obstruction are also more prone to kidney and urinary tract infections.

2.2 Patient group

There are no definitive estimates of the number of people who require a long-term ureteric stent as a result of malignant or benign ureteric strictures. In the NHS in England in 2014-15, there were 7,674 retrograde insertions and 2,733 retrograde removals of ureteric stents, but the type of stent (plastic or metallic), or the reason for insertion was not specified. The numbers of people having antegrade insertions are lower with few firm estimates currently
available. There were 80 cases of percutaneous insertions and 22 replacements of ureteric metallic stents in 2014-15.

2.3 **Current management**

People with complete ureteric obstruction require urgent referral and treatment to relieve the blockage and avoid the development of obstructive renal failure. The relief of ureteric obstruction can be achieved either by stenting the ureter, by creating a nephrostomy or by undertaking reconstructive surgery. The [NICE guideline for acute kidney injury](https://www.nice.org.uk/guidance/ph47) (AKI) states that all people with upper urinary tract obstruction should be referred to a urologist, and that when nephrostomy or stenting is undertaken, it should be done as soon as possible and certainly within 12 hours of diagnosis.

For people with malignant ureteric strictures, there are specific recommendations for those with prostate or bladder cancer. In the [NICE guideline for prostate cancer](https://www.nice.org.uk/guidance/iny79), decompression of the upper urinary tract is recommended by nephrostomy or by insertion of a double J stent for men with obstructive uropathy secondary to hormone-relapsed prostate cancer. In the [NICE guideline for bladder cancer](https://www.nice.org.uk/guidance/inf162), nephrostomy or retrograde stenting is recommended (if technically feasible) for people with locally advanced or metastatic bladder cancer with ureteric obstruction who need treatment to relieve pain, treat AKI or improve renal function before undergoing further therapy.

2.4 **Proposed management with new technology**

The Memokath 051 stent is intended for the first line treatment for adults with chronic ureteric strictures associated with benign or malignant diseases. Introducing Memokath 051 would mean limited changes to the pathway, because it would be a replacement for a double J stent or for a nephrostomy.

The adoption team has produced a scoping report for this technology.
3 Company claimed benefits and the decision problem

Details of the company’s claimed benefits and the decision problem are described in Appendix D.

Table 1 Details of variation from the scope

<table>
<thead>
<tr>
<th>Decision problem</th>
<th>Variation proposed by company</th>
<th>EAC view of the variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparator</td>
<td>Comparison with double J stents only.</td>
<td>The EAC considered all comparators in their review of the clinical evidence</td>
</tr>
</tbody>
</table>

The company proposed a variation from the scope to include only 1 comparator however the EAC considered all the comparators specified. The EAC also thought other aspects of the company’s submission did not address some of the decision problem, further details can be found in table 2.2 of the assessment report. The EAC noted that the technology is contraindicated for use in children and so the population considered was restricted to adults.

4 The evidence

4.1 Summary of evidence of clinical benefit

The company carried out 2 separate literature searches for identifying single arm and comparative studies. The EAC considered the eligibility criteria reported by the company were not in alignment with the scope, details of which can be found in section 3.2 of the assessment report. The company submission did not contain a clear description of the search methodology to enable the EAC to replicate or evaluate the search strategy. Therefore the EAC undertook a de novo literature search. Details of all the included and excluded studies are in the table below, a full description of the rationale can be found in section 3.3 of the assessment report.
Table 2 Included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of publication</th>
<th>Type of study</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies included by both EAC and company</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 studies included by both</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Studies in submission excluded by EAC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride (2017)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Studies not in submission included by EAC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Akbarov et al. (2017)</td>
<td>Abstract</td>
<td>Comparative observational study</td>
<td>Not identified by the company</td>
</tr>
<tr>
<td>Arya et al. (2001)</td>
<td>Full text</td>
<td>Observational study</td>
<td>Less than 20 patients therefore did not meet the company's eligibility criteria.</td>
</tr>
<tr>
<td>Bach et al. (2013)</td>
<td>Full text</td>
<td>Observational study</td>
<td>Excluded by the company because they could not obtain the full paper</td>
</tr>
<tr>
<td>Bolton et al. (2015)</td>
<td>Abstract</td>
<td>Comparative observational study</td>
<td>Not identified by the company</td>
</tr>
<tr>
<td>Bourdoumis et al. (2014)</td>
<td>Full text</td>
<td>Observational study</td>
<td>Excluded by the company because it includes retroperitoneal fibrosis patients.</td>
</tr>
<tr>
<td>Boyvat et al. (2005)</td>
<td>Full text</td>
<td>Observational study</td>
<td>Not identified by the company</td>
</tr>
<tr>
<td>Kim et al. (2014)</td>
<td>Full text</td>
<td>Comparative observational study</td>
<td>Excluded by the company because they could not obtain the full paper</td>
</tr>
<tr>
<td>Klarskov et al. (2005)</td>
<td>Full text</td>
<td>Observational study</td>
<td>Excluded by the company because they could not obtain the full paper</td>
</tr>
</tbody>
</table>

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Nam et al. (2015)  | Abstract  | Comparative observational study  | Not identified by the company

Papadopoulos et al. (2010)  | Full text  | Observational study  | Excluded by the company because they could not obtain the full paper

Zaman et al. (2011)  | Full text  | Observational study  | Malignant patients only, therefore did not meet the company’s eligibility criteria

**Maan et al. (2010) – company submitted Patel et al. (2011) which is the same comparative study but reports on a subgroup only. See page section 3.2 of the Assessment Report for further details.
***NCT00166361 (2014) – Granberg et al. (2010) is an associated comparative study published as an abstract identified by the EAC.
****Papatsoris et al. (2010) - company submitted Papatsoris et al. (2007), which could not be located by the EAC. EAC found Papatsoris et al. (2010) which is an updated version of the 2007 study. See section 3.3 of the assessment report for further details.

EAC critical appraisal of the clinical evidence

The EAC reviewed the clinical evidence and noted the lack of quality RCT evidence. Two studies compared Memokath-051 with double J stents (Maan et al., 2010, NCT00166361, 2014), 3 studies compared it with other metal or alloy stents Allium stents (Bolton et al., 2015), UVENTA stents (Kim et al., 2014), Resonance stents (Nam et al., 2015) and 1 study compared it with ileal ureteral replacement (IUR) (Akbarov et al., 2017). There are 10 single-arm studies all of which were published as full texts. Table 3.3 in the assessment report summarises the characteristics of each study.

The EAC conducted a critical appraisal of the evidence and concluded that all of the comparative studies and 8 of the single-arm studies were of sufficient quality and substance to provide relevant results. The EAC considered that 2 of the single-arm studies (Bach et al. 2013, Boyvat et al., 2005) did not provide acceptable levels of external validity and so discounted their results. Overall the EAC considered, the quality of evidence reported was low, mainly due to inadequate reporting of the study design, patient characteristics and
outcomes. Table 3.4 in the assessment report provides details of the EAC critique of the full text publications.

The EAC reported results for a number of outcomes in section 3.6.2 of the assessment report. Clinical success was the most widely reported outcome presented in 13 of the 14 studies reviewed. However the EAC noted the lack of a consistent definition of clinical success across the trials and therefore could not pool the results. In the comparative trials Memokath-051 had a lower clinical success rate compared with Allium stents and IUR but it had comparable rates to double J and Resonance stents. The EAC noted that 4 of the 5 comparative studies were abstracts, some with unequal group sizes. Of the single arm studies clinical success ranged from 47-100%. Table 3.6 in the assessment report provides the details of these results.

Two studies (Kim et al. 2014, Zaman et al. 2011) which the EAC deemed were well conducted and with acceptable generalisability reported stent insertion was successful in all cases.

Three comparative studies reported results of the USSQ. Memokath-051 had favourable results compared to double-J stents in relation to pain, urinary frequency, symptom bother and living with current symptoms (Maan et al., 2010). Actual outcome data were not reported in the other 2 studies but authors did report that similar results were found between Memokath-051 and Resonance stents.

Three of the 14 studies reported on length of time in situ. Of the comparative studies Kim et al. (2014) reported Memokath-051 remained in place longer than UVENTA (14 months vs 12 months). The NCT00166361 study reported Memokath-051 was in situ for 17 months compared to 4 for double-J stents. Papatsoris and Buchholz (2010) a single arm study reported Memokath-051 stayed in situ for a mean of 11 months.

Stent migration or encrustation were the most common reasons for stent removal and/or replacement. In the comparative studies, rates of stent
migration were higher in the Memokath-051 arms compared to UVENTA (43% vs 6%) (Kim et al., 2014) and double-J (11% vs 0%, Maan et al., 2010 and 7% vs 0%, NCT00166361, 2014). In the single-arm trials, rates of stent migration ranged from 8% to 46% (Arya et al., 2001 and Papadopoulos et al., 2010). In a pooled analysis (see table 3.15 of the assessment report) of migration rates Memokath-051 had the highest incidence (17.4%) compared to Allium (0%), double J (0%) and UVENTA (5.9%). Memokath-051 had higher rates of encrustation compared to Allium, 19% vs 0% (Bolton et al., 2015) and double-J stents in 1 study, 29% vs 0 (NCT00166361, 2014). In the single-arm trials, rates of encrustation ranged from 0% to 23% (Zaman et al., 2011 and Arya et al., 2001). The EAC carried out a pooled analysis (see table 3.14 of the assessment report) on encrustation rates for Memokath-051 (6.3%), however no data was available for comparator stents.

One comparative study reported on the rate of stent removal and replacement, 2 (11%) Memokath-051 stents were removed due to resolution of stricture (Maan et al., 2010). 17% of Memokath-051 stents were replaced due to a longer stent required and migration. In the single-arm studies, the majority of stents were removed, but not replaced due to encrustation (Arya et al., 2001, Bourdoumis et al., 2014, Papatsoris and Buchholz, 2010), or progressive disease (Papatsoris and Buchholz, 2010) and it is unclear whether or not they were replaced by another stent. Stent replacement was usually due to migration (Agrawal et al., 2009, Arya et al., 2001, Bourdoumis et al., 2014, Kulkarni and Bellamy, 2001, Papadopoulos et al., 2010, Zaman et al., 2011), suboptimal positioning (Kulkarni and Bellamy, 2001) and in a few cases encrustation (Agrawal et al., 2009) or progressive disease (Agrawal et al., 2009, Kulkarni and Bellamy, 2001). The EAC carried out a pooled analysis (see table 3.14 of the assessment report) on Memokath-051 stents removed (16.3%) and replaced (16%), however no data was available for comparator stents.

The EAC’s conclusions are that the evidence base is mainly small, poorly reported, observational studies meaning that all conclusions are uncertain and
could alter with new evidence. No data were available for any of the comparator stents in relation to stent removal and replacement. Clinical success and stent migration were the most commonly reported outcomes. The EAC reported clinical success was not consistently defined across the studies, which meant statistical pooling could not be conducted. Overall the current evidence suggests that Memokath-051 has similar success compared with double J and Resonance stents but worse clinical success outcomes than other comparators. Memokath-051 had improved patient-related quality of life compared with double J stents. The EAC had no significant concerns regarding adverse events for Memokath-051. The EAC considered that a large well-conducted RCT or prospective comparative study would provide more reliable estimates of the clinical effectiveness of this technology.

4.2 Summary of economic evidence

The company identified 5 studies which met their inclusion criteria, but only included 3 (Agrawal et al. 2009, Papastoris et al. 2007 and Aintree University Hospital [AUH]) in the remainder of their submission. The EAC could not replicate the company’s search because of a lack of information and noted the company’s search did not include economic resources. The EAC undertook a de novo search and identified 2 (Gonzalez et al. 2011 and Zaman et al. 2012) additional relevant studies.

The EAC considered 2 studies (Agrawal et al. 2009, Papastoris et al. 2007) identified by the company to be out of scope and excluded them. The data provided by Aintree University Hospital (AUH), Liverpool is an unpublished cost-consequence analysis comparing Memokath-051 with double-J stents. The company shared the business case document (a Microsoft PowerPoint® slide set) with the EAC. Gonzalez et al. (2011) and Zaman et al. (2012) were also cost-consequence analyses comparing Memokath-051 with double-J stents.

The EAC stated that the AUH data was unsuitable for a full critical appraisal. The estimated cost-savings assume the Memokath-051 and double-J stents...
are clinically equivalent in terms of complications and that Memokath-051 will remain insitu for 24 months. The EAC critically appraised Gonzalez et al. (2011) and found the study was poorly conducted and reported. Zaman et al. (2012) was published as an abstract only, and the EAC deemed it unsuitable for full critical appraisal. The EAC concluded that the published economic evidence was of low quality but indicated that Memokath-051 was cost saving versus double-J stents provided it remained in situ for sufficient time.

**De novo analysis**

The company presented a de novo economic model comparing Memokath-051 with double-J stents. No other comparators outlined in the scope were included. The population was all patients with chronic ureteric strictures due to both benign and malignant structures. The EAC produced a model diagram which can be found in section 4.2.2 of the assessment report. The de novo model submitted by the company was not executable and had a 2.5 year time horizon, capturing the key differences between the 2 stent types. The EAC replicated the company’s model making it fully executable and modified it to improve its usefulness. Changes included: extending the time horizon to 5 years, facilitating the model to report a break-even time point between Memokath-051 and its comparators, inclusion of reconstructive surgery and other metallic stents as comparators, assessing the risk of UTIs, revision of some inputs used by the company (see Appendix O of the assessment report), scenario analysis to model the risk of unplanned replacement of Memokath-051 stents in 4 scenarios and deterministic sensitivity analyses.
Model parameters

The parameters that were considered in the company's model and the EACs adjustments are summarised in table 3.

Table 3 Clinical parameters and costs and resources used in the company's model (taken from Assessment Report)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Memokath-051</th>
<th>Double-J stent</th>
<th>UVENTA</th>
<th>Allium</th>
<th>Resonance</th>
<th>Reconstructive surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of time in situ (no complications)</td>
<td>Company = 30 months</td>
<td>Company = 6 months</td>
<td>Company = N/A</td>
<td>Company = N/A</td>
<td>Company = N/A</td>
<td>Company = N/A</td>
</tr>
<tr>
<td></td>
<td>EAC = 60 months</td>
<td>EAC = 6 months</td>
<td>EAC = 18 months</td>
<td>EAC = 36 months</td>
<td>EAC = 12 months</td>
<td>EAC = N/A</td>
</tr>
<tr>
<td>Monthly risk for unplanned stent removal and replacement</td>
<td>Company = 0.95% (reported as 25% over 30 months)</td>
<td>0%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EAC = 1.4% (4.41% versus UVENTA)</td>
<td>0%</td>
<td>0.49%</td>
<td>0.49%</td>
<td>1.4%</td>
<td>N/A</td>
</tr>
<tr>
<td>Monthly risk of UTI</td>
<td>Company = N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EAC = 0.42% (1.25% versus surgery)</td>
<td>0.42%</td>
<td>0.42%</td>
<td>0.42%</td>
<td>0.42%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Total cost of insertion</td>
<td>Company = £3,068</td>
<td>£1,676</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EAC = £3,010</td>
<td>£786</td>
<td>£2,736</td>
<td>£2,936</td>
<td>£2,148</td>
<td>£7,414 (includes all follow-up costs)</td>
</tr>
<tr>
<td>Monthly follow-up cost</td>
<td>Company = £23.75</td>
<td>£16.67</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EAC = £42.50</td>
<td>£0</td>
<td>£42.50</td>
<td>£42.50</td>
<td>£21.25</td>
<td>N/A</td>
</tr>
<tr>
<td>Total cost of replacement</td>
<td>Company = £3,781</td>
<td>£1,676</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>EAC = £3,347</td>
<td>£1,052</td>
<td>£3,157</td>
<td>£3,357</td>
<td>£2,569</td>
<td>N/A</td>
</tr>
<tr>
<td>Cost of UTI</td>
<td>Company = N/A</td>
<td>EAC = £37.32</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results
The EAC’s revisions to the cost model show that Memokath-051 has a cost saving of £1,619 compared with double-J stents over a 5 year time horizon. Memokath-051 is estimated to be cost neutral compared with other metallic stents. When comparing Memokath-051 with reconstructive surgery, the incremental cost per patient after 5 years ranged from £467 to -£1,009 depending upon the assumptions made around the extrapolation of unplanned replacement of Memokath-051 stents. Compared with surgery, Memokath-051 is cost saving up to 53 months.

Base case results

Table 4 Company base case

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Company’s base-case</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Memokath</td>
<td>Double-J</td>
<td>Difference*</td>
</tr>
<tr>
<td>Theatre staff costs</td>
<td>£1,159.93</td>
<td>£1,159.93</td>
<td>£0.00</td>
</tr>
<tr>
<td>Theatre consumable costs</td>
<td>£1,874.16</td>
<td>£109.44</td>
<td>-£1,764.72</td>
</tr>
<tr>
<td>Procedure code/surgery tariff</td>
<td>34</td>
<td>407</td>
<td></td>
</tr>
<tr>
<td>2x Patient F/U OPD X-ray 1st 6/12 NM Renogram 2nd 6/12</td>
<td>£142.5</td>
<td>£100.00</td>
<td>-£42.50</td>
</tr>
<tr>
<td>First six months</td>
<td>£3,210.59</td>
<td>£1,776.37</td>
<td>-£1,434.22</td>
</tr>
<tr>
<td>Cost of second six month</td>
<td>£142.5</td>
<td>£1,776.37</td>
<td>£1,633.87</td>
</tr>
<tr>
<td>Total for first year</td>
<td>£3,353.09</td>
<td>£3,552.74</td>
<td>£199.65</td>
</tr>
<tr>
<td>Cost for second year</td>
<td>£285</td>
<td>£3,552.74</td>
<td>£3,267.74</td>
</tr>
<tr>
<td>total for two years</td>
<td>£3,638.09</td>
<td>£7,105.48</td>
<td>£3,467.39</td>
</tr>
<tr>
<td>Cost of last six months</td>
<td>£142.5</td>
<td>£1,776.37</td>
<td>£1,633.87</td>
</tr>
<tr>
<td>total cost for 2.5 years</td>
<td>£3,780.59</td>
<td>£8,881.85</td>
<td>£5,101.26</td>
</tr>
<tr>
<td>Risk factor 25%</td>
<td>945.15</td>
<td>0</td>
<td>-945.15</td>
</tr>
<tr>
<td><strong>Total cost per treatment/patient over 2.5 years with calculation of risk</strong></td>
<td>4,725.74</td>
<td>£8,881.85</td>
<td>£4,156.11</td>
</tr>
</tbody>
</table>

* A minus sign indicates device is more expensive than the comparator in this cost category.
EAC base case results

Memokath-051 versus double-J stents

Table 5 EAC base case results by component (per patient over 5 years)

<table>
<thead>
<tr>
<th></th>
<th>Memokath-051</th>
<th>Double-J Stents</th>
<th>Incremental cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total insertion cost</td>
<td>£3,010</td>
<td>£786</td>
<td>£2,224</td>
</tr>
<tr>
<td>Follow-up cost</td>
<td>£2,346</td>
<td>£0</td>
<td>£2,346</td>
</tr>
<tr>
<td>Unplanned replacement cost</td>
<td>£2,503</td>
<td>£0</td>
<td>£2,503</td>
</tr>
<tr>
<td>Planned replacement cost</td>
<td>£0</td>
<td>£8,692</td>
<td>-£8,692</td>
</tr>
<tr>
<td>Adverse event cost</td>
<td>£9</td>
<td>£9</td>
<td>£0</td>
</tr>
<tr>
<td>Total</td>
<td>£7,868</td>
<td>£9,487</td>
<td>-£1,619</td>
</tr>
</tbody>
</table>

Breakeven point = 30 months

The EAC’s model showed savings of at least £1,619 over 5 years with Memokath-051 compared to double-J stents. Across all scenarios, in patients who require a stent for at least 30 months, Memokath-051 is cost saving versus double-J stents.

Memokath-051 versus reconstructive surgery

The incremental cost per patient after 5 years ranged from £467 to -£1,009 depending upon the assumptions made around the extrapolation of unplanned replacement of Memokath-051 stents.

Memokath-051 versus other metallic stents

Planned stent replacement is the key factor in comparisons between Memokath-051 and other metallic stents. The EAC carried out a costs over time (see Appendix R of the assessment report) analysis. Over time, the lines on these graphs consistently cross. Therefore, Memokath-051 is judged to be cost neutral compared to UVENTA and Allium in the worst case, but may generate cost savings with more positive assumptions (i.e. no unplanned replacements after 2 years). Compared with Resonance, Memokath-05 was cost saving after 12 months. The EAC advised caution in relation to cost
comparisons for both Allium and Resonance as these results are based on assumptions not comparative clinical data.

**Sensitivity analysis**

The company did not include any sensitivity analyses in their submission although they stated that the key drivers of the model are the cost of stents versus the in situ time of the stent. The EAC conducted univariate sensitivity analysis to assess the impact of parameter uncertainty on the results of the model (values and ranges can be found in Appendix S of the assessment report).

The EAC considered various scenarios relating to unplanned stent replacement (for all stents). These are outlined in section 4.4 of the assessment report. Memokath-051 versus double-J stent the results are sensitive to the procedure costs to replace double-J stents and the risk of unplanned replacements with Memokath-051. For Memokath-051 compared with reconstructive surgery in the worst case scenario (i.e. constant risk of unplanned Memokath-051 replacement over 5 years) the model is highly sensitive to many input values. In the best case scenario (i.e. no risk of unplanned replacement after 2 years) the model is most sensitive to the cost of surgery, the risk of unplanned replacement up to 24 months and the planned time in situ. Compared with the other metallic stents, results were most sensitive to the risk of unplanned replacement with Memokath-051 stents. In the best case scenario, results were typically favourable to Memokath-051, whilst in the worst case there was far more uncertainty.

The EAC concluded that the economic evidence were poorly reported, but indicated that Memokath-051 is likely to be cost saving versus double-J stents provided that Memokath-051 remains in situ for sufficient time. The EAC could not find any evidence on the cost-effectiveness of Memokath-051 versus any other comparators.
5 Ongoing research

The company and the External Assessment Centre did not identify any ongoing studies on Memokath-051.

6 Issues for consideration by the Committee

Clinical evidence

- Considering the number of years Memokath-051 has been on the market, the clinical evidence for Memokath-051 is of poor quality. There is an absence of powered comparative data and uncertainties around what is deemed a clinical success. No comparative data comparing Memokath-051 with nephrostomy was identified.

- There is a disparity between the company and clinical experts regarding patient selection. Due to the quality of the evidence the subgroup analysis provides little clarity on the appropriate population.

- Some uncertainty around clinical evidence supporting the claims in terms of fewer stent-related symptoms and complications compared to some comparator devices.

Cost evidence

- Memokath-051 is cost saving or cost neutral depending on the comparator, however this is based on patient selection, length of time Memokath-051 is in situ and patient life expectancy. The EAC concluded that Memokath-051 is cost saving up to month 53 compared with reconstructive surgery and in patients not eligible for reconstructive surgery that require a stent for at least 30 months. Both these timeframes are dependent on life expectancy and the length of time the stent remains in situ.
7 Authors

Liesl Millar, Technical Analyst

Bernice Dillon, Technical Advisor

Mark Campbell, Associate Director

NICE Medical Technologies Evaluation Programme

July 2017
Appendix A: Sources of evidence considered in the preparation of the overview

Details of assessment report:


Submissions from the following sponsors:

- PNN Medical

Related NICE guidance:


References


AUH Cost-effectiveness of using permanent Memokath Stent (MMK) compared to JJ stent. Aintree University Hospital.
Assessment report overview: The Memokath-051 stent for the treatment of ureteric obstruction

July 2017


Assessment report overview: The Memokath-051 stent for the treatment of ureteric obstruction

July 2017


Nam, J., Han, J., Lee, D., Park, S. & Chung, M. 2015. Comparison of initial experiences between full-length metallic stent and segmental metallic stent in malignant ureteral obstruction. World Congress of Endourology & SWL Annual Meeting

NCT00166361 2014. Drainage of Malignant Extrinsic Ureteral Obstruction Using the Memokath Ureteral Stent.


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Assessment report overview: The Memokath-051 stent for the treatment of ureteric obstruction

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PNN Medical 2016. Memokath 051CW: Instructions for Use [Not publicly available].


Assessment report overview: The Memokath-051 stent for the treatment of ureteric obstruction

July 2017
Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Mr Matthew Shaw
Consultant Urologist, British Association of Urological Surgeons

Mr Mahmoud Elfar
Consultant Urologist, British Association of Urological Surgeons

Mr Peter Guy
Consultant Urologist, British Association of Urological Surgeons

Mr Ranan Das Gupta
Consultant Urologist, British Association of Urological Surgeons

Ms Daniela Andrich
Consultant Urological Surgeon, British Association of Urological Surgeons

Professor Tony Mundy
Professor of Urology, British Association of Urological Surgeons

6 expert questionnaires were received with 4 urologists having experience of using Memokath-051.

The technology and its use

- 3 experts stated MK-051 had a unique design, but other metallic stents available
- 2 experts would only use in benign cases if unfit for surgery
- 1 expert would use if life expectancy >6 months; 1 expert would only use in palliative malignancy with limited life expectancy
Patient benefits

- 5 experts stated fewer stent changes than double-J stent, with associated reduced anaesthetics
- 3 experts: improved patency with fewer stent symptoms vs. double-J
- 1 expert: more tolerated than nephrostomy

System benefits

- Reduced admissions and theatre time for stent changes
- 1 expert: shorter stay and morbidity than open surgery

Costs

- Increased cost of stent (need to stock various sizes), but cost-saving over long-term (18 months)

Other comments

- These stents can still block and migrate: follow-up needed
- Expertise needed: only in specialist centres
- 1 expert stated JJ stents are most commonly used in NHS for both malignant and benign, as not every patient is referred to specialists for reconstructive urological surgery
- Patient selection is important
- 2 experts: long term of Memokath-051 stents and repeated use in benign strictures who are fit for surgery are at a higher risk of complications
Appendix C: Comments from patient organisations

Advice and information was sought from patient and carer organisations. The following patient organisations were contacted and no response was received.

- Action on Bladder Cancer
- Bladder and Bowel Foundation
- British Kidney Patient Association
- Everyman
- Fight Bladder Cancer
- Helen Rollason Cancer Charity
- Help the Hospices
- Jo's Trust
- Kidney Cancer UK (KCUK)
- Kidney Research UK
- Macmillan Cancer Support
- Maggie's Centres
- Marie Curie
- National Council for Palliative Care
- Ovacome
- Ovarian Cancer Action
- Pelvic Pain Support Network
- Polycystic Kidney Disease Charity
- Prostate Cancer UK (formerly prostate cancer charity)
- Rarer Cancers Foundation
- Sue Ryder
- Tackle Prostate Cancer
- Target Ovarian Cancer
- The Eve Appeal
- The Robin Cancer Trust
Appendix D: Claimed benefits and decision problem

The claimed patient benefits for Memokath-051 are:

- A safe, simple and reliable ureteric stent that is better tolerated by the patient, with fewer stent-related symptoms and complications
- Avoids the need for replacement procedure surgery every 6 months requiring anaesthesia and overnight hospital stays
- Restores dignity and improves quality of life
- Reduced risk of tissue ingrowth
- Reversibility of procedure if needed with no side effects.

The claimed benefits to the healthcare system for Memokath are:

- Efficient use of theatre time as no major surgery is needed
- Significant cost savings by avoiding surgery every 6 months requiring anaesthesia and overnight hospital stays, with less social care needed
- Reversibility of procedure if needed.

<table>
<thead>
<tr>
<th>Scope issued by NICE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
</tbody>
</table>
| **Comparator(s)**                         | Double J stents
|                                            | Nephrostomy
|                                            | Reconstructive surgery
|                                            | Metallic and alloy stents (including nitinol stents)
|                                            | (see also ‘Cost analysis’ below) |
| **Outcomes**                              | The outcome measures to consider include: |
|                                            | Number and rate of replacement stents |
|                                            | Number and rate of repeat procedures requiring anaesthesia and surgery |
|                                            | Theatre time and hospital stay |
|                                            | Quality of life including patient tolerability and comfort |
|                                            | Length of time stent remains in situ |
|                                            | Clinical success rate (e.g. improved renal function, no obstruction) |
|                                            | Frequency of stent removal/reversal |
### Assessment report overview: The Memokath-051 stent for the treatment of ureteric obstruction

**July 2017**

- Device-related adverse events including procedure related complications and information pertaining to the resource use associated with these adverse events
- Frequency of follow-up visits
- Pain scores including from subsequent bladder irritation

#### Cost analysis

**Comparator(s):**
- Double J stents
- Nephrostomy
- Reconstructive surgery
- Metal and alloy stents

Costs will be considered from an NHS and personal social services perspective.

The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.

Sensitivity analysis will be undertaken to address uncertainties in the model parameter.

#### Subgroups to be considered

- Patients unfit for surgery
- Malignant or benign stricture
- Antegrade or retrograde insertion (including the procedure performed either by an interventional radiologist or a urologist)

#### Special considerations, including those related to equality

Some ureteric obstructions are a result of malignancy - all people with cancer are protected under the Equality Act from the point of diagnosis. People with ureteric strictures may benefit from Memokath-051 as an alternative to double J stents, as it may be associated with a reduced number of replacement procedures and reduced adverse events, which would improve their quality of life. Memokath-051 may also provide an alternative treatment for people with ureteric strictures who cannot tolerate or who have had failed conventional stents, who would otherwise be nephrostomy-dependent and are likely to be classed as disabled under the Equality Act.

#### Special considerations, specifically related to equality issues

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?</td>
<td>No</td>
</tr>
<tr>
<td>Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?</td>
<td>No</td>
</tr>
<tr>
<td>Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?</td>
<td>No</td>
</tr>
</tbody>
</table>