National Institute for Health and Care Excellence

Medical technologies evaluation programme

Memokath 051 Ureter stent for ureteric obstruction (update of MTG35)
Consultation comments table

Final guidance panel meeting date: 16 September 2022 14:30

There were 4 consultation comments from 1 consultee.

The comments are reproduced in full.

#	Consultee ID	Role	Section	Comments [sic]	NICE response
1	1	Manufacturer (other)	3.14	When comparing Memokath-051 to JJ, Allium or Resonance, pooled data is used to derive monthly probability of Memokath-051 unplanned stent replacement of 1.8% including the newly identified studies data from Bier 2017, Khoo 21 and Forster 2021, although data from the newly identified Choi et al 2019 was not included in the pool. The risk of unplanned stent replacement for Resonance and Allium has been derived from Khoo et al 2021. When comparing Memokath-051 to Uventa, data from Choi et al 2019 alone is used to inform monthly probability of stent change, of 3.57% and 5.54% respectively for Memokath-051 Uventa. This is change from using only Kim et al 2014 in the original guidance. It is unclear why these two methods are used to inform Memokath-051 monthly probability of stent change. In the original rationale for this mixed methodology, due to lack of comparative studies available for Memokath-051 and Allium or Resonance is no longer relevant. It is appreciated that a	Thank you for your comment. The panel considered your comment carefully and was advised by the EAG that the monthly unplanned stent replacement risk for Memokath 051 Ureter was 1.8% when compared with double-J, Allium and Resonance. This was derived from data reported in 3 new European studies (Bier et al. 2017, Khoo et al. 2021 and Forster et al. 2021) along with the 9 studies included in the original guidance (Agrawal et al. 2009, Arya et al. 2001, Bourdoumis et al. 2014, Kulkarni and Bellamy 1999, Maan et al. 2010, Papadopoulos et al. 2010, Papatsoris and Buchholz 2010, Zaman et al. 2011, Kim et al. 2014). A separate monthly risk of Memokath 051 Ureter was estimated at 3.57% when compared UVENTA. The estimate was based on data from Choi et al. (2017) which

				few concerns regarding the Khoo et 2021 study, namely the follow up period was short and stent survival was reported. It should be noted that follow up of the UK study Khoo 2021 is 18-30 months for Memokath-051 a follow up representative of other studies. • Can the impact of using the data from the UK comparative study for Memokath-051, Allium and Resonance in the base case modelling be investigated and shared? • Can the impact of including the Choi et al 2019 stent failure data into the pooled data used against Allium and Resonance be investigated and shared? • Has pooled data for Memokath-051 been considered when comparing to Uventa? It is appreciated that variations in risk of unplanned stent change have been covered in the sensitivity analysis performed. However, as the base case cost savings are published in this NICE guidance for named devices, accuracy wherever possible advised as these inaccuracies may result in over or underestimating costs saving being published by NICE.	reported a direct head-to-head comparison. Amendments were made to section 3.14 to improve clarity. When estimating the risk of unplanned Memokath 051 Ureter replacement, all data reported in the single arm and comparative studies were included. The panel acknowledged that Khoo et al. (2021) had a short follow-up time but it is a UK study, and considered to be reasonable to include it in the pooled estimate. The panel was also aware of the assessment report update reporting that the estimated monthly probability would be 1.54% if Khoo et al. (2021) was excluded. The sensitivity analysis was done by varying the study inclusion, and the results of these analyses did not change the overall cost saving conclusions. The panel noted that Choi et al. (2019) was a retrospective comparative study that directly compared Memokath 051 Ureter and UVENTA. The EAG explained that when evidence on a direct comparison is available, data from the study is used to estimate the monthly risk of Memokath 051 Ureter unplanned replacement in the absence of any UK based studies. The panel was advised by the EAG that if the results from Choi et al. (2019) were pooled with the other Memokath 051 Ureter studies, the monthly probability of unplanned stent replacement changes from 1.8% to 2.3%. This higher value was covered in the range explored in sensitivity analyses. When applied in the cost model for a 5-year time horizon as a scenario, the conclusion of the base case remained unchanged with cost savings for Memokath 051 Ureter compared with double-J stents, Allium and Resonance but costs incurred for Memokath 051 Ureter compared with surgery. Regarding the query on pooled data for Memokath 051 Ureter compared to UVENTA, a range from 0.0% to 6.5% has been explored in the sensitivity analysis and this includes the pooled estimates for Memokath 051 Ureter, and Memokath 051 Ureter is cost saving compared to UVENTA in all scenarios.

					The draft guidance (section 3.16) reported the base case results. Sections 3.17 and 3.18 described the key drivers for the cost case and reported the EAG's sensitivity analyses. The sensitivity analyses around the unplanned risk of stent replacement in 3.17 have been emphasised.
2	1	Manufacturer (other)	3.14	Several unvalidated assumptions for the other metal stents are used in the modelling, these could cause issues in the base case estimates presented, resulting in an over or under estimate of the base case cost savings reported. • The use of a passport balloon dilator has been assumed for all metal stents. Inclusion of such a device was submitted by the for Memokath-051 and corroborated for the Allium stent. Use was assumed for Resonance and UVENTA. Resonance is a 6Fr device (same a JJ) and does not require the use of a balloon passport, this is an additional £193 cost per initial stent insertion and every stent change which has been added to EAC base case but is not required for Resonance. This assumption was made in the original model and has not been changed. Please can the base case for Resonance be changed to remove the balloon dilator. • A procedure time of 37.5 minutes has been assumed for all comparator metal stents based on two clinical experts. However, literature indicates a shorter insertion time for Resonance of circa 21 min (Patel et al. BMC Urology (2017) DOI 10.1186/s12894-017-0204-08). As Resonance is a metal stent with double pigtails and similar insertion method, timings close to the standard JJ are more suitable. Please can the base case for Resonance be changed to and insertion times like double-JJ. • The stent replacement time for Memokath-051 is the same as all metal stents. This does not appear to have been verified by clinicians. Memokath-051 requires the device to be cooled to shrink the stent for removal whereas other stents do not this is likely to drive an overestimation of replacement costs for theatre time and staff costs for other metal stents. Resonance replacement is very similar to double-JJ. Please can the replacement times used for Resonance be more like double-JJ	Thank you for your comment. The panel was advised by the EAG that in the original assessment report, a passport balloon dilator (£193) was needed when inserting Memokath 051 Ureter, and the assumption was that the use of a dilator was also needed when inserting UVENTA and Resonance stents. The EAG reviewed the new evidence and found that only one study (Bier et al. 2017) reported using a dilator before the Memokath 051 Ureter placement. Responding to the comment, the EAG ran an analysis excluding the passport balloon dilator cost from the consumables cost for Resonance, and the saving using Memokath 051 Ureter decreased from £6,260 to £5,392 compared with Resonance. But the overall cost saving conclusion for Memokath 051 Ureter remained unchanged. The panel understood that in the original assessment, 2 clinical experts provided advice on procedure time, suggesting that the average insertion time for double-J stents was 22.5 minutes (ranging between 15 minutes to 30 minutes) and the average insertion time for metallic stents was 37.5 minutes (ranging between 30 minutes to 45 minutes). The studies included in the update reported on procedure time. The EAG reviewed Patel et al. (2017) which reported the 21 minutes insertion time was a median with a large range (12 to 90 minutes) and the study had a small sample size. Responding to the comment, the EAG ran an analysis applying a procedure time of 21 minutes for Resonance, and the cost saving using Memokath 051 Ureter decreased from £6,260 to £6,057 compared with

				It is appreciated that these points have been covered in the sensitivity analysis performed. However, as the base case cost savings are published in this guidance for named devices, accuracy wherever possible advised as these inaccuracies may result in over or underestimating costs saving in base case being published.	Resonance. When applying the stent insertion procedure time of double-J stent (22.5 minutes) for the Resonance insertion, the saving using Memokath 051 Ureter decreased from £6,260 to £6,076 compared with Resonance. But the overall cost saving conclusions for Memokath 051 Ureter remained unchanged. The panel was advised by the EAG that the stent replacement time (75 minutes) for Memokath 051 Ureter in the cost case was based on the company inputs and expert opinion in the original assessment, and this was assumed to be the same for other metal stents, except double-J stent (55 minutes). Responding to the comment, the EAG applied the stent replacement time of double-J stent for Resonance stent replacement and found that the cost savings of using Memokath 051 Ureter dropped from £6,260 to £5,157 compared with Resonance. But Memokath 051 Ureter remained a cost saving option.
3	1	Manufacturer (other)	3.16	Here the guidance states that Memokath-051 is cost saving and quotes the EAC base cases. Throughout the rest of the document the guidance highlights how the cost savings are uncertain (sections 1.2, 4.10 and 4.11). If section 3.16 is read in isolation this offers a potential misrepresentation of the uncertainties in the model base cases. Propose this section also highlights the uncertainty in cost saving estimates.	Thank you for your comment. The draft guidance (section 3.16) reported the base case results. The EAG ran a series of sensitivity analyses to address the potential uncertainties in the model. Sections 3.17 and 3.18 reported the key driver for the cost case. The uncertainty of the cost case was also acknowledged in section 1 of the draft guidance. The sections shouldn't be read in isolation. The panel decided not to make any changes to the guidance.
4	1	Manufacturer (other)	3.16	Stent replacement is raised as a key driver in the costs for this model. Has the risk of double counting, for the metal stents which also have a risk of unplanned stent change included, been thoroughly investigated and mitigated from the model? A planned stent change has been included for other metal stents at 12, 18 and 24 months respectively for Resonance, Uventa and Allium in accordance with device IFUs. Cumulative costs in appendix R (of the original EAC report) demonstrate clear jumps in costs at 12, 18 and 24 monthly intervals for the other metal stents accordingly. This indicates the model automatically allocates a planned stent change at	Thank you for your comment. The panel was advised by the EAG that both unplanned and planned stent replacements were considered in the cost model. The monthly risk of unplanned replacement has been calculated using the standard formula (Drummond et al., as used in the original guidance) with the number of events occurring during the study period, reported in the literature. This is a standard modelling method to run the model for a longer time horizon (5 years). Scenario analyses were done to address the potential uncertainties; for example, replacement in the

				these time intervals compared with initial insertion, irrespective of unplanned stent change occurring. For these other metal stents the EAC have applied a constant unplanned replacement rate to the other metal stents. If for example a stent fails at 11 months for Resonance and the model triggers all stents are replaced at 12 months this would result in double counting for stents which have been replaced due to failure. However, clinically, a stent failure would reset the planned replacement countdown. The stepwise nature of the results indicating that “resetting” has not been included in the model Any double counting could result in an over or underestimation in savings. Could the risk of double counting be checked and impact on base case updated accordingly if required.	first 2 years with 0% thereafter, reduced replacement after 2 years (risk halved) and constant unplanned replacements over a 2-year time horizon. Furthermore, the model considered that if an unplanned stent replacement was done, then it automatically would push the planned replacement by the length of time in situ. Therefore, no “double counting” would affect the overall conclusion of the cost case.