NICE National Institute for Health and Care Excellence

Health Tech programme

DG100867: Pulmonary artery pressure technologies for remote monitoring of chronic heart failure

Draft Guidance Collated Comments

Theme 1 – Clinical effectiveness

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
1	Consultee 1 University Hospital Southampton NHS Trust	Has all of the relevant evidence been taken into account?	We have shared our data (22 patients followed up for 2 years) with Abbott who I believe have shared this data with you. This paper is in the process of being submitted to Heart, showing very impressive outcome data in the NHS. We showed a large reduction in admission along with high compliance and that interactions with HF team fall substantially after the first year.	Thank you for sharing this draft paper with us. This study, if published, would not have met the EAG inclusion criteria for clinical effectiveness, which was restricted to RCTs for evidence on relative effects. The EAG broadened inclusion criteria to include prospective multi-centre single arm trials that reported device-related outcomes (implant or sensor failure or device related complications). As this study is a single-centre case series it would not be eligible for inclusion. The EAG included COAST-UK which reported UK data. It also appears likely that there is overlap between participants from these two studies as COAST-UK is a multi-centre UK based study with enrolment covering a similar timepoint (March 2017 to November 2018 in this paper July 2017 and October 2018 in COAST-UK) and authors from Southampton were included in the COAST-UK study.

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				This before-and-after study does contain results relevant to monitoring, however it is not clear how patients were selected for CardioMEMS implantation, and there is no control group. The study confirms that medication changes, including dose escalation, was common. The study also found that there was a reduction in number of reviews by a heart failure nurse in the year after implant compared to the year before, but there was an increase in the number of reviews by a heart failure consultant. So, whilst the number of reviews was unchanged overall, there was a difference in who was conducting the reviews, which would have a cost implication. As only absolute numbers of events are reported, the EAG assumes that the findings do not account for those who died, as the rate of review per patient year is not reported.
2	Consultee 1 University Hospital Southampton NHS Trust	1.2 Should not be used	From a clinical perspective this guidance is very disappointing. Having used cardiomems for the last 8 years we have seen first hand how effective it is and the positive impact on patients and their carers.	Thank you for your comment. The committee has recommended that CardioMEMs can be used as an option for remote monitoring of NYHA class III heart failure after considering additional modelling results.
3	Consultee 1 University Hospital Southampton	1.2 Why the committee made these recommendations	The people in the trials are not necessarily younger than those in the NHS. This is a matter of patient selection. There is also no reason to suggest that the technology wouldnt work regardless of age.	Thank you for your comment. This text has been removed from the guidance.

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	NHS Trust			
4	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations Selected text: *non-adherence to the monitoring schedule and changes to medication*	The studies consistently show high compliance with taking readings. We have data on 22 patients implanted mostly as part of COAST study. Readings were submitted daily with 2 year FU data showing 93% success rate for uploading data confirming high compliance in an NHS situation. Patients responded to changes in medication. HF hospitalisations were dramatically reduced from a total of 47 in the year to implant, to 7 in year 1 postimplant and 2 in the second year	Thank you for your comment. Adherence to using the device is reported in section 5.5.2.6 of the external assessment report. Please see response to comment 1 for why this study was not eligible for inclusion. A small study of 22 patients is unlikely to have changed the findings for this outcome where there are data from 3 large CardioMEMS trials, and there is also the potential overlap with the COAST-UK study that mean that data from at least some of these patients may already be included in the clinical effectiveness review.
5	Consultee 1 University Hospital Southampton NHS Trust	3.7 CardioMEMS Selected text: *people in the trial were younger than the real-world UK chronic heart failure population*	This is always true in clinical trials, CardioMEMS is no different from HF drug and device trials which show similar trends. It is also a matter of patient selection - The device would be chosen for the most suitable patients.	Thank you for your comment. The text has been removed from the guidance.
6	Consultee 1 University Hospital Southampton NHS Trust	3.19 The cost effectiveness of CardioMEMS Selected text: *The committee*	This is not true based on data from multiple real world studies showing consistent results with the trials	Thank you for your comment. The text has been removed from the guidance.

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		agreed that the clinical effectiveness was likely greater in the trials than in the real-world clinical setting		
7	Consultee 2 British Society for Heart Failure	Has all of the relevant evidence been taken into account?	The relevant evidence has been taken into account. Comment by [redacted]	Thank you for your comment.
8	Consultee 3 Individual	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	50/50	Thank you for your comment.
9	Consultee 3 Individual	Are the recommendations sound and a suitable basis for guidance to the NHS?	NO	Thank you for your comment.
10	Consultee 5 Leeds Teaching Hospitals NHS Trust	Has all of the relevant evidence been taken into account?	No please see comments	Thank you for your comment.
11	Consultee 5 Leeds Teaching	Are the summaries of clinical and	I don't believe so. Please see comments below.	Thank you for your comment.

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	Hospitals NHS Trust	resource savings reasonable interpretations of the evidence?		
12	Consultee 7 Individual	Has all of the relevant evidence been taken into account?	Yes	Thank you for your comment.
13	Consultee 7 Individual	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Please see my comments.	Thank you for your comment.
14	Consultee 7 Individual	Are the recommendations sound and a suitable basis for guidance to the NHS?	Please see my comments.	Thank you for your comment.
15	Consultee 8 Swansea Bay University Health Board	Has all of the relevant evidence been taken into account?	Yes	Thank you for your comment.
16	Consultee 11 Heart Failure Warriors NI	Has all of the relevant evidence been taken into account?	Answer: We believe so.	Thank you for your comment.
17	Consultee 12 Individual	Are the recommendations	No, the patient population is grossly over estimated	Thank you for your comment. The EAG's economic modelling is based on

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		sound and a suitable basis for guidance to the NHS?		an individual patient who is eligible for implantation, and as such does not depend on the volume of patients who would be eligible. Please see response to comment 132 for further detail.
18	Consultee 13 Abbott Medical	Has all of the relevant evidence been taken into account?	Abbott believe that all relevant information has been appropriately taken into account	Thank you for your comment.
19	Consultee 13 Abbott Medical	3.5 Study size, quality and populations	"The sample sizes of the studies included for the main review of clinical effectiveness outcomes ranged from 15 people (in SIRONA) to 1,000 people (in GUIDE-HF). The mean or median age of people in the studies ranged from 61 to 71 years across the studies. This is younger than the average age of people with first heart failure diagnosis in the UK, which is 77 years." "The committee also noted that the technologies could have been more effective in the studies than they will be in routine clinical practice because of the younger age of the study participants." Abbott disagrees with these statements, as none of the trials applied an upper age limit for inclusion. The younger age profile observed reflects routine clinical practice, shaped by physician selection and a patient population with lower overall frailty. Real-world use of CardioMEMS aligns with the experience seen in the trials and therefore, Abbott suggests revising the statement to: "The committee noted that the recruited patients in the	Thank you for your comment. The text "The committee also noted that the technologies could have been more effective in the studies than they will be in routine clinical practice because of the younger age of the study participants." has been deleted from the guidance. The text "The sample sizes of the studies included for the main review of clinical effectiveness outcomes ranged from 15 people (in SIRONA) to 1,000 people (in GUIDE-HF). The mean or median age of people in the studies ranged from 61 to 71 years across the studies. This is younger than the average age of people with first heart failure diagnosis in the UK, which is 77 years." remains in the guidance as we believe this is factually correct, however it is not listed as a limitation of the evidence in section 3.7.

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			trials were younger than the average NHS heart failure patient, but this is likely to reflect a heart failure population with reduced frailty."	
20	Consultee 13 Abbott Medical	3.9 CardioMEMS compared with Cordella	"The committee discussed that there was not enough evidence to show whether the 2 technologies could be considered to be equivalent. One clinical expert advised that this was unknown because the data for Cordella was limited and that there was also only limited real-world experience with the technology" Abbott agrees with these comments and strongly recommends that the data under review be considered device-specific, without assuming equivalence between different devices.	Thank you for your comment
21	Consultee 13 Abbott Medical	3.19 The cost effectiveness of CardioMEMS	"The committee agreed that the clinical effectiveness was likely greater in the trials than in the real-world clinical setting." Abbott disagrees with this comment as multiple real-world studies, including the Post-Approval Study in the United States (US-PAS), have demonstrated outcomes consistent with clinical trial findings and in some cases, an even more pronounced impact.	Thank you for your comment. The EAG note in their report that real world evidence studies were only included for device-related outcomes, as explained in the inclusion criteria (see section 4.1 in the EAG assessment report). The clinical effectiveness evidence was restricted to randomised comparisons which provides the most robust evidence of clinical effectiveness.
22	Consultee 14 Individual	Has all of the relevant evidence been taken into account?	Yes	Thank you for your comment.
23	Consultee 15 British Cardiovascular Society	Has all of the relevant evidence been taken into account?	Yes	Thank you for your comment.

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24	Consultee 10 Edwards Lifesciences	Has all of the relevant evidence been taken into account?	Yes, the relevant evidence for the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System has been taken into account	Thank you for your comment.
25	Consultee 10 Edwards Lifesciences	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Yes, the summaries for the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System are reasonable interpretations of the evidence reviewed.	Thank you for your comment.
26	Consultee 10 Edwards Lifesciences	Are the recommendations sound and a suitable basis for guidance to the NHS?	Edwards Lifesciences considers the recommendations to be a fair reflection of the evidence presented for the the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System	Thank you for your comment.
27	Consultee 12 Individual	Has all of the relevant evidence been taken into account?	Different device types have been amalgamated and this may skew the results	Thank you for your comment. Outcome data for CardioMEMS HF System and Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System has not been amalgamated in the clinical or cost effectiveness analyses. Evidence for the 2 technologies has been considered separately.
28	Consultee 12 Individual	Are the summaries of clinical and resource savings	The donot think usual care should be compared with usual care and cardiomems. Instead usual care should eb comapred with cardiomems ony	Thank you for your comment. The committee discussed whether PAP technologies replace usual care for monitoring. The committee recognised

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		reasonable interpretations of the evidence?		that some aspects of usual care can be replaced (for example, some outpatient appointments for assessment of fluid status) but did not believe that all aspects of usual care for monitoring would be replaced by PAP technologies. In the studies, PAP technology did not completely replace usual care. Therefore the committee did not agree that PAP technologies alone vs usual care would be the appropriate comparison. The committee also agreed that it is difficult to quantify the aspects of usual care that would be replaced by PAP technologies. The committee acknowledged the uncertainty in relation to this, and a description has been added in section 3.19 of the guidance.
29	Consultee 4 University Hospitals Dorset	Has all of the relevant evidence been taken into account?	The assessment group appears to treat remote and PAP monitoring as additional to standard care, rather than as an alternative model of care delivery. This overestimates the cost of PAP monitoring.	Thank you for your comment. Please see response to comment 28.
30	Consultee 4 University Hospitals Dorset	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Treating PAP monitoring as an add-on to, rather than a re-design of, standard care inflates the apparent cost. In the NHS, PAP-guided management replaces some face-to-face reviews and unplanned admissions; it is not simply “extra monitoring.”	Thank you for your comment. Please see response to comment 28.
31	Consultee 4 University Hospitals	Are the recommendations sound and a	Treat PAP monitoring as an integrated alternative to standard care, not an additional layer.	Thank you for your comment. Please see response to comment 28.

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	Dorset	suitable basis for guidance to the NHS?		
32	Consultee 5 Leeds Teaching Hospitals NHS Trust	2.3 2 Information about the technologies	The current model assumes that PAP monitoring is an addition cost to the standard HF care pathway. However in reality it is likely that in a selective group of patients PAP monitoring can replace existing parts of the HF pathway but not scheduling frequent clinic visits to assess symptoms as we can use PAP monitoring to flag when reviews may or may not be needed particularly in stable patients. This also enables care to perhaps be delivered remotely or over the telephone instead of requiring the patient to attend for face to face review to assess fluid status.	Thank you for your comment. Please see response to comment 28.
33	Consultee 6 Barts Health NHS Trust	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Also, the model assumes CardioMEMS is entirely “add-on” activity. In reality, it replaces a lot of what we currently do: fewer urgent clinic slots, fewer ad-hoc phone calls, and of course, fewer emergency admissions. Those substitutions are real resource savings that haven’t been accounted for. The projected number of eligible patients per hospital also feels high compared with what most of us are seeing in the early adopter phase; it’s more likely to be single or low double figures per year, not 50+. That makes a big difference when you model staffing and overheads. So while the summaries capture the right message, the magnitude of both benefit and cost feels skewed, the benefit understated, and the workload overstated.	Thank you for your comments. Please see response to comments 17 and 28.

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34	Consultee 6 Barts Health NHS Trust	Are the recommendations sound and a suitable basis for guidance to the NHS?	The story that CardioMEMS reduces admissions and improves patient stability is well supported by both trial data and real-world experience. But I don't think the resource impact is represented quite as it plays out on the ground. The assumption of very intensive ongoing monitoring (three times a week, indefinitely, with full restart after every medication change) doesn't reflect how services actually run. In practice, we focus on close follow-up early on and then taper down to a light-touch review pattern. Once stable, it becomes part of the background of their heart failure management, not a full extra clinic. Also, the model assumes CardioMEMS is entirely "add-on" activity. In reality, it replaces a lot of what we currently do: fewer urgent clinic slots, fewer ad-hoc phone calls, and of course, fewer emergency admissions. Those substitutions are real resource savings that haven't been accounted for. At Barts, we've developed a CardioMEMS pathway that works well: Structured follow-up early after implantation, Integration into our existing HF remote monitoring system, and a shared MDT review for any concerning trends. The system adds a safety net rather than a burden. Our experience shows that this can be delivered sustainably with the right set-up.	Thank you for your comments. Please see response to comments 47 and 48 regarding monitoring schedule. Please see response to comment 28 regarding the place of the technology in the care pathway. Please see response to comment 17 about the size of the patient population.

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			Additionally, the projected number of eligible patients per hospital also feels high compared with what most of us are seeing in the early adopter phase; it's more likely to be single or low double figures per year, not 50+. That makes a big difference when you model staffing and overheads. So while the summaries capture the right message, the magnitude of both benefit and cost feels skewed, the benefit understated, and the workload overstated.	
35	Consultee 13 Abbott Medical	2.3 2 Information about the technologies	"The aim of PAP technologies is to supplement usual monitoring for chronic heart failure." Abbott disagrees with this statement and the approach taken in the current base-case model, which estimates a standard heart failure care pathway and then adds CardioMEMS monitoring on top. This results in a combined cost of all standard care activities plus those associated with CardioMEMS, which Abbott believes does not accurately reflect clinical practice. In reality, CardioMEMS monitoring can replace certain elements of the standard care pathway for stable patients and should not be considered merely an "add-on." Therefore, we recommend that the wording be revised to reflect this more integrated and realistic use of CardioMEMS in clinical care.	Thank you for your comment. Please see response to comment 28. The text has been amended to clarify that the technology can replace some aspects of usual care for monitoring.
36	Consultee 13 Abbott Medical	3.10 All-cause mortality	"All-cause mortality was evaluated in the 3 RCTs on CardioMEMS and in the comparative and single-arm phases of PROACTIVE-HF and SIRONA 2 on Cordella."	Thank you for your comment. Text in the guidance has been amended.

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			Abbott disagrees with this statement, as it incorrectly implies that the studies were powered to assess mortality outcomes. We recommend revising the wording to: "All-cause mortality was evaluated as a secondary endpoint in the three RCTs on CardioMEMS, as well as in the comparative and single-arm phases of PROACTIVE-HF and SIRONA 2 for Cordella."	

Theme 2 – Quality of life impact

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
37	Consultee 1 University Hospital Southampton NHS Trust	3.11 Quality of life Selected text: *MONITOR-HF reported an increase in EQ-5D-5L score and GUIDE-HF reported a decrease.*	MONITOR-HF showed a clear benefit on QOL. This trial was in a European setting and shows the benefits of CardioMEMS in a similar healthcare system from our own	Thank you for your comment. Please see section 5.5.6.1 of the external assessment report for more information about quality of life outcomes.
38	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations	MONITOR-HF (Lancet): primary endpoint was the KCCQ overall summary score at 12 months. MONITOR-HF reported a mean between-group difference ≈ +7.05 points (95% CI 2.77–11.33), p=0.013 in favour of CardioMEMS — this is statistically	Thank you for your comment. This is reported in the clinical effectiveness review (Figure 7) in the external assessment report. Quality of life has been included in the model. Please see

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			significant and clinically meaningful. Improvements to QOL should be taken into account in any model.	response to comment 39 for further details.
39	Consultee 4 University Hospitals Dorset	Has all of the relevant evidence been taken into account?	It remains unclear to what extent health-related quality of life has been incorporated, despite this being a key outcome in studies such as MONITOR-HF. I suggest that more real-world evidence from NHS services currently using PAP monitoring should be included to provide a fairer and more accurate picture.	Thank you for your comment. Health-related quality of life is included in the model. Data from MONITOR-HF is included for the first 12 months and state-based utilities are included beyond 12 months. State-based utilities were used to model the benefits beyond 12 months because the data required to do linear extrapolation of the MONITOR-HF data beyond 12 months is not available. Please see the assessment report and addendum for further details. Real-world data would not meet the inclusion criteria for the quality of life outcome.
40	Consultee 4 University Hospitals Dorset	Are the recommendations sound and a suitable basis for guidance to the NHS?	Fully account for improvements in health related quality of life shown in studies such as MONITOR-HF. Until these changes are made, the conclusions around cost-effectiveness and overall value may not be reliable.	Please see response to comment 39.
41	Consultee 11 Heart Failure Warriors NI	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? Answer: As patients we have concerns that our views have not been taken fully into account nor the impact of remote monitoring on how our care is delivered. We welcome technology that has the potential to reduce the number of hospital appointments that we have to attend as well as those which have been proven to	Thank you for your comment and for describing the impact of outpatient appointments and hospitalisations. Please see response to comment 28 regarding the potential of the technologies to reduce routine appointments.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			reduce the number of hospitalisations to treat heart failure. Outpatient appointments are disruptive, can require taking time off work in addition to significant journey time. Maintaining the same standard of monitoring through remote means would significantly benefit our quality of life. Being hospitalised for heart failure has a significant impact on our lives, those of our families as well as our mental wellbeing. Once hospitalised we live with a fear of further hospitalisation and the remote monitoring described in this assessment has the potential to provide us with peace of mind that our risk of further hospitalisation has been reduced.	
42	Consultee 11 Heart Failure Warriors NI	Are the recommendations sound and a suitable basis for guidance to the NHS?	Are the recommendations sound and a suitable basis for guidance to the NHS? Answer: We do not believe that the assessment has accurately represented the impact of PAP monitoring on the delivery of care and a patient's quality of life and therefore the recommendations are inappropriate.	Thank you for your comment.
43	Consultee 9 Individual	Has all of the relevant evidence been taken into account?	For the most part, I think the committee has taken all of the relevant evidence into account. My one comment would be that there is little in the way of acknowledgement of improved quality of life associated with the pulmonary artery pressure monitor as found in MONITOR-HF.	Thank you for your comment. Please see response to comment 39.
44	Consultee 9 Individual		I do not agree that the recommendations are sound based on my comments expressed regarding quality of life not being taken into account , incorrect assumption of the level of care required on a day to day basis for those with a pulmonary artery pressure monitor and flaws in the health economic analysis.	Thank you for your comment. Please see responses to comments 28 and 39 regarding care pathway and quality of life. Please see responses to comments 48 and 70 regarding the health economic analysis.

Theme 3 – Monitoring schedule

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
45	Consultee 1 University Hospital Southampton NHS Trust	3.18 Healthcare professional costs Selected text: *The clinical experts explained that the frequency of monitoring is likely to reduce after the initial implant.*	This is most definitely true	Thank you for your comment.
46	Consultee 1 University Hospital Southampton NHS Trust	3.18 Healthcare professional costs Selected text: *The clinical experts explained that the frequency of monitoring is likely to reduce after the initial implant.*	Strongly agree. This is definitely true in our cohorts. We saw a large drop off in a clinical interactions in year 2 compared to year 1 post implant	Thank you for your comment.
47	Consultee 1 University Hospital Southampton NHS Trust	3.18 Healthcare professional costs Selected text:	The definition of this requires close consideration. The schedule should not reset with simple medication changes which occur regularly in stable patients. It would only reset with clinical decompensation - best defined as a heart failure hospitalisation.	Thank you for your comment. The committee discussed this issue and recognised that not all medication changes are due to treatment escalation, and that using this definition

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		The monitoring schedule would be repeated from the start if heart failure worsens.		will overestimate the proportion of patients requiring more frequent monitoring. The committee also recognised that in some cases, worsening heart failure could be treated outside of hospital, for example virtual wards and hospital at home. So using hospitalisation for heart failure could underestimate the proportion of patients requiring more frequent monitoring. The committee acknowledged the uncertainty and considered it as part of decision making. This has been described in section 3.19 of the guidance.
48	Consultee 9 Individual	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	this is the most troubling aspect of the draft guidance from my perspective. I think the assumed input required in the pulmonary artery pressure monitor cohort is overstated. I think 3 x10 minute consultations per week for the first 3 months is at the very conservative end (in correctly selected patients this might need to be the case for only six weeks). Thereafter, the principle of the device/system is that ongoing follow-up is reactive/alert-based. Routine checking-in with the patient might only need to happen once every 4-6 weeks and even less frequently (every 3 months) in the more stable patients used to using the device.	Thank you for your comment. The committee discussed the appropriate monitoring schedule and agreed to accept the scenario with a monitoring schedule as follows: at calibration, week 1, week 2, week 3 and then once every 3 months for a patient with stable heart failure. Please see scenario 4 in the addendum and section 3.19 of the guidance.
49	Consultee 1 University Hospital Southampton	Are the summaries of clinical and resource savings	We believe that the assumptions made in the model are incorrect. specifically that monitoring requirements have been overestimated significantly. The model should be redone with more realistic requirements in	Thank you for your comment. Please see responses to comments 63 and 68 and point 1 in the EAG assessment report addendum. The EAG

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	NHS Trust	reasonable interpretations of the evidence?	line with the committee's recommendations. The committee stated that 'the monitoring schedule would be repeated from the start if heart failure worsens' (3.18). However, the EAG has interpreted this as 'if the patient needs escalation of treatment, the cycle begins again. This is not what happens in clinical practice. Medication changes occur on stable patients with no impact on monitoring frequency. The cycle would begin again in patients who have had a heart failure decompensation (best defined as an admission to hospital). It also seems that there is an assumption of 7 reviews per patient per month - this is grossly excessive. Most patients in the monitoring phase need no reviews (alert-based actions only).	acknowledge that the assumptions in the updated EAG base-case differ from the committee preferred assumptions described in the draft guidance. However, the EAG worked with NICE and the clinical expert members of the committee to create a scenario that reflected their preferences. All assumptions were checked and agreed with them. Please note that the updated model provided during consultation was not the final model. 7 reviews per month is an average over those who are stable (and receive 1 monitoring check per month) and those who are not and revert to the more intensive 12 checks per month. The proportion with the more intensive checks is based on the proportion with medication changes from the RCTs. In the final model the EAG provided an additional scenario where monitoring would be increased following a heart failure hospitalisation. See scenario 5 in the addendum for further details and results.
50	Consultee 1 University Hospital Southampton NHS Trust	Are the summaries of clinical and resource savings reasonable interpretations of	Overestimation of monitoring costs in the model appear to have had a major effect on the model and we strongly recommend that the model is redone on more realistic monitoring schedule. We do not support the current recommendation and suggest that the committee reconsider to approve use to cardiomems.	Thank you for your comment. Please see response to comment 48.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		the evidence?		
51	Consultee 1 University Hospital Southampton NHS Trust	3.18 Healthcare professional costs Selected text: *The committee thought that adjusting the monitoring costs in the model would be unlikely to reduce the ICER sufficiently for CardioMEMS to fall within the range that NICE considers a cost-effective use of NHS resources*.	The monitoring costs appear to have been grossly overestimated.	Thank you for your comment. Please see response to comment 48.
52	Consultee 1 University Hospital Southampton NHS Trust	3.19 The cost effectiveness of CardioMEMS Selected text: *The results of the economic model suggested that the ICER for CardioMEMS in*	The costs of monitoring have been grossly overestimated and I suspect this is incorrect.	Thank you for your comment. Please see response to comment 48. Section 3.19 of the guidance has been updated to include the results of the final model (scenario 4 in the addendum).

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		the probabilistic base-case analysis was £41,878 per QALY gained.		
53	Consultee 1 University Hospital Southampton NHS Trust	3.19 The cost effectiveness of CardioMEMS Selected text: *The committee concluded that, given the cost of CardioMEMS, accounting for these uncertainties in the model would be insufficient to make it cost effective.*	This statement is likely incorrect based on the grossly overestimated monitoring costs.	Thank you for your comment. Please see response to comment 48. Section 3.19 of the guidance has been updated to align with the final model results (scenario 4 in the addendum).
54	Consultee 1 University Hospital Southampton NHS Trust	3.22 Health Technology Wales model	I understand that the new model has been built using the assumption that any medication change should reset the monitoring schedule. This is not what happens in clinical practice. Monitoring schedules are reset following a heart failure decompensation (usually defined by hospitalisation). Medication changes occur in stable patients commonly without this altering the monitoring schedule. The model should be redone taking this into account.	Thank you for your comment. Please see previous responses on assumptions around monitoring frequency (comment 63 and 68). We have now provided a final model with an additional scenario where monitoring would be increased following a heart failure hospitalisation. See the addendum for further details and results.
55	Consultee 2	Are the	The reported clinical summary is a reasonable	Thank you for your comment. Following

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	British Society for Heart Failure	summaries of clinical and resource savings reasonable interpretations of the evidence?	interpretation of the evidence. However, the resource savings presented do not seem to align with clinical experience. The committee's conclusions (3.21) about patient monitoring frequency and pattern does reflect the clinical reality. However, the EAG seems to have misinterpreted the committee's guidance: The committee recommended calibrating the technology following sensor implantation, with weekly monitoring during weeks 1, 2, and 3, followed by monitoring every three months. However, the EAG adopted a once-a-month monitoring schedule after the third month, which diverges from the committee's guidance and may impact the validity of the model's assumptions. The committee stated that 'the monitoring schedule would be repeated from the start if heart failure worsens' (3.18). However, the EAG has interpreted this as 'if the patient needs escalation of treatment, the cycle begins again.' Escalation of treatment is common in clinical practice and is mostly performed on stable patients – it does not necessarily indicate worsening heart failure which would be better defined by admission to hospital or need for clinical review. In clinical practice, monitoring is not routinely escalated or restarted following simple medication changes. It would be more accurate to use hospitalisation due to heart failure for resetting the optimisation phase The assumption of seven monitoring reviews per patient, per month is higher than what is observed in clinical practice and does not align with the	the first committee meeting, further discussion about the monitoring schedule took place and an updated version of the model was made available to stakeholders. This was not the final version of the model. Scenario 4 of the final version of the model does include the monitoring schedule of monitoring at calibration, week 1, week 2, week 3 and then once every 3 months for a patient with stable heart failure. Please see the addendum and section 3.19 of the guidance.

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			committee's recommendation for an 'appropriate monitoring schedule The need for medication changes is typically highest in the first 12 months following an implant and decreases after that substantially, and the assumption of a constant, ongoing requirement for monitoring does not reflect clinical practice. Input in the second and ongoing years is often minimal unless there has been an acute decompensation/hopitalisation. Comment by [redacted]	
56	Consultee 2 British Society for Heart Failure	Are the recommendations sound and a suitable basis for guidance to the NHS?	The assumptions outlined above are likely to result in unrealistic excess costs of monitoring which undermine the validity of the ICER. This should be addressed, and the model revised accordingly to ensure the resulting guidance is robust and reflective of clinical practice. Comment by [redacted]	Thank you for your comment. The EAG agrees that results are sensitive to assumptions around monitoring frequency, and this is therefore a key uncertainty for the committee to consider. Please see response to comment 55.
57	Consultee 4 University Hospitals Dorset	Has all of the relevant evidence been taken into account?	I am concerned that not all relevant real-world evidence and user experience have been fully considered in the current assessment. Although elements of the narrative and cost-effectiveness model have been updated following feedback, the three documents available on the NICE website do not always align. This makes it unclear what assumptions and variables underpin the current model. In particular: The model's assumptions about the ongoing management and review frequency for NYHA Class III	Thank you for your comment. Please see response to comment 55.

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			heart failure patients with pulmonary artery pressure (PAP) monitoring do not reflect real-world practice.	
58	Consultee 4 University Hospitals Dorset	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	I do not believe the summaries of clinical and resource savings fully reflect real-world experience. The current cost-effectiveness model assumes that after optimisation, patients continue to receive around seven PAP data reviews per month indefinitely. In practice, once pressures are stable, review frequency reduces substantially — often to once every few weeks or even months. The model therefore overestimates clinician time and associated cost.	Thank you for your comment. Please see response to comment 55.
59	Consultee 4 University Hospitals Dorset	Are the recommendations sound and a suitable basis for guidance to the NHS?	Not yet. The recommendations are based on a model that may not reflect the true operational and clinical realities of PAP monitoring in NHS heart failure care. To be suitable for NHS guidance, the model needs to: Reflect actual patterns of review once patients are stable post-implant.	
60	Consultee 5 Leeds Teaching Hospitals NHS Trust	3.18 Healthcare professional costs	While the PAP monitoring suggested in this document would mirror the planned real world monitoring The updated model assumes that any medication change would then mean a return to 'intense' monitoring as per the post implant phase. In our cohort of patients this would be unlikely to reflect practice and we would be unlikely to intensify follow up in this situation and would continue based on alerts or patients symptoms. For example in our heart patients with devices we would largely rely on alert based monitoring following medication changes. This therefore likely	Thank you for your comment. As explained in point 1 of the addendum, the EAG produced the updated analyses following a request by NICE. That request stated that “The cycle starts again if a patient becomes unwell and needs escalation of treatment.” This is why the updated EAG model linked intensification of monitoring to changes in medication. The committee discussed that changes in medication may not always be to escalate treatment, and so this may over-estimate intensification of

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			overestimates long term costs.	monitoring. The EAG have created an additional scenario reflecting the situation where a more intense monitoring schedule is only applied when a patient is hospitalised rather than following medication changes. The results from this scenario are provided in the addendum (scenario 5).
61	Consultee 6 Barts Health NHS Trust	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	The story that CardioMEMS reduces admissions and improves patient stability is well supported by both trial data and real-world experience. But I don't think the resource impact is represented quite as it plays out on the ground. The assumption of very intensive ongoing monitoring (three times a week, indefinitely, with full restart after every medication change) doesn't reflect how services actually run. In practice, we focus on close follow-up early on and then taper down to a light-touch review pattern. Once stable, it becomes part of the background of their heart failure management, not a full extra clinic.	Thank you for your comment. Please see responses to comments 47 and 48.
62	Consultee 7 Individual	Not specified	I have read the document, there is huge effort went into this. I have a few comments: - The required monitoring for CardioMEMS is less than what stated in this document.	Thank you for your comment. Please see response to comment 48.
63	Consultee 13 Abbott Medical	Are the summaries of clinical and resource savings reasonable interpretations of	While the clinical summary appears to be a reasonable interpretation of the evidence, the resource savings presented do not align with clinical reality. Abbott fully supports the committee's conclusions in section 3.21 regarding patient monitoring frequency	Thank you for your comment. This comment covers two issues related to resources for monitoring, the first about frequency of monitoring, and the second about when to re-intensify monitoring.

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		the evidence?	and patterns, which reflect actual practice within NHS trusts. However, we are concerned that the EAG has misinterpreted the committee's guidance when implementing these recommendations in the health economic model. This misinterpretation has likely introduced inaccuracies that affect the reliability of the resulting Incremental Cost-Effectiveness Ratio (ICER). Key concerns include: Monitoring Frequency: The committee recommended "calibrate the technology after sensor implantation, then monitor weekly for the weeks 1, 2 and 3, then monitor every 3 months." However, the EAG model includes "12 monitoring sessions in the first three months after implantation, then switching to a once a month schedule after the third month.". The EAG modelling deviates from the committee's guidance and therefore compromises the validity of the model's assumptions. Definition of Disease Progression: The committee stated that the monitoring schedule should restart if heart failure worsens (section 3.18). The EAG interpreted this as restarting the schedule whenever treatment is escalated. Abbott does not support this interpretation, as escalation of treatment does not necessarily indicate worsening heart failure. In clinical practice, monitoring is not routinely restarted following medication changes. We recommend using hospitalisation due to heart failure as a proxy for disease progression, consistent with real-world evidence. Monitoring Volume: The resulting assumption of seven monitoring sessions per patient, per month is significantly higher than what is observed in clinical	For the frequency of monitoring issue, the EAG updated their base-case in response to a request from NICE to reflect the committee's preferences. The EAG requested some clarification on the committee's preferences from NICE, which led to some discussion between the clinical experts on the committee as to their preferences. The assumptions that they then agreed upon are what the EAG implemented in their updated model. This is why there is a discrepancy between the committee preferences stated in the draft guidance and what the EAG assumed in their updated model. Please see point 1 in the addendum for a more detailed response on this issue. Please note that this updated model does not represent the final model. For the point around intensification of monitoring, as noted in the response to 3.18 above, the request from NICE to the EAG was to intensify "if a patient becomes unwell and needs escalation of treatment". To be able to implement this the EAG needed an estimate of the proportion of patients for whom treatment is escalated per month. This information was available in GUIDE-HF and MONITOR-HF; we asked for advice on which was most appropriate, and

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			practice and does not reflect the committee's recommendation for an "appropriate monitoring schedule." Medication Adjustment Assumptions: The EAG's assumptions regarding the frequency of medication changes are based on GUIDE-HF and MONITOR-HF studies, both with 12-month follow-up periods, and these rates have been extrapolated indefinitely in the model. Abbott would like to highlight that the need for medication adjustments typically declines over time, and assuming a constant long-term monitoring requirement does not reflect clinical reality.	heard that an average would be reasonable. The EAG note that this could be an over-estimate of intensification in the longer term, although if intensification is linked to hospitalisations, then it would be expected these increase over time as patients have more recurrent heart failure hospitalisations. The EAG ran an additional scenario where monitoring is only intensified following a hospitalisation. The results from this scenario are provided in the accompanying addendum (scenario 4)
64	Consultee 13 Abbott Medical	Are the recommendations sound and a suitable basis for guidance to the NHS?	In reference to our response to Question 2, Abbott find the current recommendation to be insufficiently robust and therefore unsuitable as a basis for NHS guidance. The EAG appears to have misinterpreted the committee's intent regarding an 'appropriate monitoring schedule' (section 3.18) and this misinterpretation should be formally addressed (and the model revised) to ensure that any resulting guidance is both methodologically sound and reflective of real-world clinical practice.	Thank you for your comment. The final model included a scenario (scenario 4) which aligned with the monitoring schedule described in the draft guidance. Please see the addendum for more information.
65	Consultee 13 Abbott Medical	3.18 Healthcare professional costs	"The clinical experts explained that the frequency of monitoring is likely to reduce after the initial implant. So, the frequency of 3 times per week used in the model over the lifetime was likely an overestimate." Abbott strongly agrees with this comment and emphasises that the monitoring frequency assumed in the model is significantly overestimated and does not	Thank you for your comment. The committee discussed monitoring frequency and agreed to accept scenario 4 of the final model, which has a reduced monitoring frequency for patients with stable heart failure. The model does not capture the more frequent monitoring required for patients

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			reflect real-world practice. While the protocol used in the initial model aligns with Abbott's recommendations for the immediate post-implant period, it is far too frequent for stable patients, as discussed during Committee Meeting 1. Following GDMT optimisation, real-world experience shows that PAP monitoring frequency decreases substantially and remains low in stable patients. Abbott would like to highlight that this overestimation has a considerable impact on the ICER and is a key driver of the draft outcome. To ensure the ICER accurately reflects clinical practice, we recommend that the committee take into account real-world experience from clinicians in England currently monitoring patients with CardioMEMS.	with unstable heart failure. This has been described in section 3.19 of the guidance.
66	Consultee 13 Abbott Medical	3.18 Healthcare professional costs	"The committee agreed that the appropriate monitoring schedule would be to calibrate the technology after sensor implantation, then monitor weekly for the weeks 1, 2 and 3, then monitor every 3 months. The monitoring schedule would be repeated from the start if heart failure worsens." Abbott strongly agrees with this statement and appreciates that our initial concern has been acknowledged. However, we do not believe the updated model shared with stakeholders on 14th November accurately reflects the committee's "appropriate monitoring schedule" and the CardioMEMS monitoring frequency remains significantly overestimated. We are particularly concerned that the committee's intended schedule has	Thank you for your comment. The EAG have subsequently provided a final model which incudes a scenario that aligns with this monitoring schedule. Please see response to comment 68 with regard to use of medication change data in the model.

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			been misinterpreted, resulting in the new model assuming 7 x ten-minute monitoring sessions per patient, per month, 21 times higher than the frequency recommended by the committee. Abbott strongly disagrees with the EAG's interpretation that any change in heart failure medication indicates worsening heart failure. We recommend that heart failure hospitalisation events be used as the appropriate indicator of disease worsening, in line with real-world studies. It is important to clarify that CardioMEMS is designed to support proactive management of heart failure, and management adjustments do not equate to disease deterioration. One of the key benefits of CardioMEMS is its ability to provide early alerts, enabling timely medication changes before the patient's heart failure worsens or they become symptomatic. In light of this, Abbott strongly disagrees with the assumption in the new model that the monitoring schedule should restart with every medication change as this does not reflect clinical practice. Furthermore, the frequency of medication changes used in the model is based on GUIDE-HF and MONITOR-HF studies with 12-month follow-up, yet has been extrapolated indefinitely. Abbott would like to highlight that the need for medication adjustments typically declines over time, making the assumption of a constant long-term monitoring requirement inaccurate and likely to overestimate costs. The committee recommended "calibrate the technology after sensor implantation, then monitor weekly for the weeks 1, 2 and 3, then monitor every 3 months." However, the EAG model includes "12	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			monitoring sessions in the first three months after implantation, then switching to a once a month schedule after the third month.". The EAG modelling deviates from the committee's guidance and therefore compromises the validity of the model's assumptions. Given these inaccuracies and the significant impact of PAP monitoring costs on the overall cost-effectiveness outcome, Abbott strongly recommends that the model be re-run using the committee's intended monitoring schedule. We also urge the committee to seek input from clinicians in England currently monitoring CardioMEMS patients, as they can provide valuable real-world insights into monitoring practices around medication changes.	
67	Consultee 13 Abbott Medical	3.19 The cost effectiveness of CardioMEMS	"The results of the economic model suggested that the ICER for CardioMEMS in the probabilistic base-case analysis was £41,878 per QALY gained. This is above the range that NICE considers an acceptable use of NHS resource. All iterations of the probabilistic sensitivity analysis resulted in more health at a higher cost for CardioMEMS. The committee concluded that CardioMEMS was not cost effective at its current price." Abbott considers this conclusion to be premature and potentially unfair, given that multiple committee-recommended changes to the base-case have not yet been incorporated or re-run to assess their impact. As outlined above, when Abbott re-ran the model using the committee's recommendations (as detailed in section 3.21), the resulting ICER was £16,649 per QALY, with a 68.1% probability of being cost-effective at a £20,000 per QALY threshold. This indicates that	Thank you for your comment. The EAG have provided a final model which implements relevant changes to the base case, resulting in an ICER of £14,0237 per QALY gained.

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			CardioMEMS is cost-effective at its current price.	
68	Consultee 13 Abbott Medical	3.21 Preferred model assumptions for this evaluation	"• use the cost of monitoring based on the monitoring schedule that was considered plausible by the committee (see section 3.22)." Abbott strongly agrees with this statement and appreciates that our initial concern has been acknowledged. However, we do not believe the updated model shared with stakeholders on 14th November accurately reflects the committee's "appropriate monitoring schedule." and the CardioMEMS monitoring frequency remains significantly overestimated. We are particularly concerned that the committee's intended schedule has been misinterpreted, resulting in the new model assuming 7 x ten-minute monitoring sessions per patient, per month, 21 times higher than the frequency recommended by the committee. Abbott strongly disagrees with the EAG's interpretation that any change in heart failure medication indicates worsening heart failure. We recommend that heart failure hospitalisation events be used as the appropriate indicator of disease worsening, in line with real-world studies. It is important to clarify that CardioMEMS is designed to support proactive management of heart failure, and management adjustments do not equate to disease deterioration. One of the key benefits of CardioMEMS is its ability to provide early alerts, enabling timely medication changes before the patient's heart failure worsens or they become symptomatic. In light of this, Abbott	Thank you for your comment. For the frequency of monitoring issue, the EAG updated their base-case in response to a request from NICE to reflect the committee's preferences. The EAG requested some clarification on the committee's preferences from NICE, which led to some discussion between the clinical experts on the committee as to their preferences. The assumptions that they then agreed upon are what the EAG implemented in their updated model. This is why there is a discrepancy between the committee preferences stated in the draft guidance and what the EAG assumed in their updated model. Please see point 1 in the addendum for a more detailed response on this issue. For the intensification of monitoring, as noted in the response to 3.18 above, the request from NICE to the EAG was to intensify "if a patient becomes unwell and needs escalation of treatment". To be able to implement this the EAG needed an estimate of the proportion of patients for whom treatment is escalated per month. This information was available in GUIDE-HF and MONITOR-HF; we asked for advice on which was

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			strongly disagrees with the assumption in the new model that the monitoring schedule should restart with every medication change as this does not reflect clinical practice. Furthermore, the frequency of medication changes used in the model is based on GUIDE-HF and MONITOR-HF studies with 12-month follow-up, yet has been extrapolated indefinitely. Abbott would like to highlight that the need for medication adjustments typically declines over time, making the assumption of a constant long-term monitoring requirement inaccurate and likely to overestimate costs. The committee recommended "calibrate the technology after sensor implantation, then monitor weekly for the weeks 1, 2 and 3, then monitor every 3 months." However, the EAG model includes "12 monitoring sessions in the first three months after implantation, then switching to a once a month schedule after the third month.". The EAG modelling deviates from the committee's guidance and therefore compromises the validity of the model's assumptions. Given these inaccuracies and the significant impact of PAP monitoring costs on the overall cost-effectiveness outcome, Abbott strongly recommends that the model be re-run using the committee's intended monitoring schedule. We also urge the committee to seek input from clinicians in England currently monitoring CardioMEMS patients, as they can provide valuable real-world insights into monitoring practices around medication changes.	most appropriate, and heard that an average would be reasonable. The EAG acknowledge that this could be an over-estimate of intensification in the longer term, although if intensification is linked to hospitalisations, then it would be expected these increase over time as patients have more recurrent heart failure hospitalisations. The EAG ran an additional scenario where monitoring is only intensified following a hospitalisation. The results from this scenario are provided in the addendum.

Theme 4 – Cost effectiveness

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69	Consultee 1 University Hospital Southampton NHS Trust	3.16 Heart failure hospitalisation rates Selected text: *So, the committee concluded that it was possible that heart failure hospitalisation rate may have been underestimated or overestimated*	It is highly likely that the Lahoz study underestimates risk of heart failure hospitalisations when compared with a group with prior hospitalisation who remain Class III despite best medical therapy. This will underestimate the potential benefits of cardiomems	Thank you for your comment. Please see response to comment 71 for information about heart failure hospitalisation rates in the model.
70	Consultee 9 Individual	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Secondly, the data used for the health economic analysis for heart failure hospitalisations and mortality did not take into account the NYHA classification. Those in NYHA class I and II have considerably lower rates of both heart failure hospitalisation and mortality and subsequent resource utilisation. They would not be considered for a pulmonary artery pressure monitor. Those in groups one and two should not have formed part of the analysis.	Thank you for your comment. The analysis was specific to people with NYHA class III heart failure. all outcome data was for people with NYHA class III. Please see response to comment 71 for information about heart failure hospitalisation rates in the model.
71	Consultee 5 Leeds Teaching Hospitals NHS Trust	3.16 Heart failure hospitalisation rates	The model used to Lahoz et al (2020) study to estimate the probability of HF hospitalisations and mortality. However this does not take into account NYHA Class. This therefore repsresnets a more heterogenous group that the highly symptomatic NYHA III patients that have recurrent hospitalisations and therefore have the most to benefit from CardioMEMS. t. As Lahoz et al (2020) includes all	Thank you for your comment. The Lahoz data was used to inform the hazard ratios for those with 1, 2, or 3 previous recurrent heart failure hospitalisations relative to the hazard ratio for heart failure hospitalisations for those with no recurrent heart failure hospitalisation (i.e. those in state Stable HF1). It was

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			patients with a HF diagnosis in the primary care record, it represents a more heterogenous patient population than the highly symptomatic NYHA III group indicated for CardioMEMS.	not used directly to inform the baseline heart failure hospitalisation rate in Stable HF1 itself. Instead, the EAG used the COAST UK population data to inform the baseline heart failure hospitalisation rate in Stable HF1, which is based on NYHA III patients. However, this data included patients who had more than one recurrent heart failure hospitalisation, and so the EAG used the Lahoz estimates to adjust the COAST UK estimate so that it reflects those in the Stable HF1 state. The EAG did however find an error in its adjustment calculation which has now been corrected. Please see the EAGs detailed response in point 2 of the addendum. .
72	Consultee 13 Abbott Medical	3.10 All-cause mortality	"The RCT results suggested a small decrease in mortality with CardioMEMS." Abbott agrees with this comment and would like to emphasise that the observed “small decrease in mortality with CardioMEMS” has not been incorporated into the model base-case, which assumes a hazard ratio of 1. This highlights the conservative anchoring of the base-case modelling and introduces additional uncertainty into the outcomes.	Thank you for your comment. The uncertainty surrounding reductions in all-cause mortality have been described in section 3 of the guidance.
73	Consultee 13 Abbott Medica	3.17 Utilities	“In scenario 6c, utilities were used from MONITOR-HF for the first 12 months, and health-state based utilities were used for extrapolation beyond 12 months. This	Thank you for your comment. The EAG used Scenario 6c from the original modelling in its updated base-case in

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			scenario analysis resulted in an ICER of £36,000 per QALY gained for CardioMEMS. The committee concluded that scenario 6c was the most plausible of the analyses considered." Abbott appreciates that our initial concern was acknowledged and led to the adoption of updated utility values in the new model (Scenario 6c). However, we believe that limiting the application of these utilities to the first 12 months underestimates the longer-term impact on patient quality of life. While clinical studies have demonstrated improvements in quality of life up to 12 months, real-world experience suggests that these benefits are sustained beyond that period. This highlights the conservative anchoring of the model's base-case and introduces additional uncertainty into the outcomes.	line with the committee's preference. There is no data on utilities beyond 12 months, and so assumptions are required. The EAG model bases utilities on health-state beyond 12 months. This does allow for a continued utility benefit of CardioMEMS beyond 12 months, because CardioMEMS reduces heart failure hospitalisations and hence slows patients progression through the model health-states which differ in utility.
74	Consultee 13 Abbott Medical	3.21 Preferred model assumptions for this evaluation	"The committee concluded that the base case in this evaluation must:" Abbott broadly agrees with the committee's conclusions, however, we do not believe that the updated model shared with stakeholders on 14th November accurately reflects these changes.	Thank you for your comment. The final model captures these changes. Please see the addendum for further details.
75	Consultee 13 Abbott Medical	3.21 Preferred model assumptions for this evaluation	"• adopt the approach to utilities used in scenario 6c (that is, use utilities from MONITOR-HF for the first 12 months and use health-state based utilities for extrapolation of utilities beyond 12 months)"	Thank you for your comment. Please see response to comment 73.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Abbott appreciates that our initial concern was considered, leading to the adoption of updated utility values in the new model (Scenario 6c). However, we believe that limiting the application of these utilities to the first 12 months underestimates the longer-term impact on patient quality of life. While clinical studies have demonstrated improvements up to 12 months, real-world experience indicates that these benefits are sustained beyond this period. This highlights the conservative anchoring of the model's base-case and introduces additional uncertainty into the outcomes.	
76	Consultee 14 Individual	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Yes, but I think the confidence around economic modelling is over-stated. There are large assumptions in the models that could change the conclusion.	Thank you for your comment.
77	Consultee 14 Individual	3.16 Heart failure hospitalisation rates	Agree that HF hospitalisation rates could have been overestimated or underestimated. In particular, the population of patients in CPRD are very elderly (age 80) and have frequent comorbidities. There are probably not reflective of the type of patients who would be offered device-based management of heart failure - typically younger and less co-morbid. It is hard to know whether the results of economic modelling are reliable given the uncertainty about the risk of recurrent HF hospitalisation in the population that might be treated with a CardioMEMS device.	Thank you for your comment.
78	Consultee 1 University Hospital	1.2 Should not be used	I believe this is incorrect, cost effectiveness data is supportive of its use. It is a proven technology which reduces hospital admissions and improves patients	Thank you for your comment.

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	Southampton NHS Trust	Selected text: *CardioMEMS does not offer value for money and should not be used in the NHS.*	quality of life	
79	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations Selected text: *Results from the economic modelling of CardioMEMS show that it is not cost effective.*	Martin Cowie has published Cost-effectiveness data. I can only assume your modelling is incorrect.	Thank you for your comment. Differences in model structure, assumptions, and model inputs can lead to different results. The EAG report clearly describes previous cost-effectiveness modelling studies that have been conducted, the assumptions that they make, and the differences between them. It also clearly provides the rationale for the model structure, assumptions and inputs used by the EAG in the model. Section 7.5.2 of the EAG report gives a comparison of the results from different modelling studies, including the Cowie studies. The EAG note that the main reason that the results differ to the Cowie study is due to the way that utilities and monitoring costs are modelled.
80	Consultee 4 University Hospitals Dorset	Has all of the relevant evidence been taken into account?	The population used for estimating hospitalisation rates does not represent the higher-risk NYHA III subgroup who are typically eligible for CardioMEMS. This underestimates hospitalisation risk in standard care and therefore under-represents the potential benefit of PAP monitoring.	Thank you for your comment.

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81	Consultee 4 University Hospitals Dorset	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	Using a broader “primary care heart failure population” for modelling hospitalisations does not reflect the NYHA III group most likely to receive CardioMEMS. For example, COAST study data show an average of 1.52 hospitalisations in the year before implant — much higher than the current model assumes. This underestimates the impact and cost savings of PAP monitoring. Overall, the model’s assumptions about frequency of monitoring, comparator care, and hospitalisation rates lead to a conservative and unrealistic estimate of resource use and benefit.	Thank you for your comment. Please see responses to comments 71, 47 and 48.
82	Consultee 4 University Hospitals Dorset	Are the recommendations sound and a suitable basis for guidance to the NHS?	Use a hospital-based NYHA III population to estimate hospitalisation risk.	Thank you for your comment. Please see response to comment 71.
83	Consultee 5 Leeds Teaching Hospitals NHS Trust	Are the recommendations sound and a suitable basis for guidance to the NHS?	No I believe there is a population of patients (which is small and limited to NYHA 3 patients) who will benefit from CardioMEMS and therefore I believe it is cost effective and should be approved.	Thank you for your comment.
84	Consultee 6 Barts Health NHS Trust	Has all of the relevant evidence been taken into account?	Broadly, yes. The main trials are there, and the document reflects the overall direction of evidence quite fairly. Where I think it misses the mark a little is how that evidence has been translated into the model. The “baseline” population used feels too healthy compared with the patients we actually see who are	Thank you for your comment. The Lahoz data is used in the modelling to estimate the increase in heart failure hospitalisation rate depending on how many previous heart failure hospitalisations a patient has had. It is not used for the baseline heart failure

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			suitable for CardioMEMS. The reliance on datasets like Lahoz et al. means you're effectively modelling a general heart failure population, not the repeatedly admitted, symptomatic NYHA III group this technology is really aimed at. That inevitably underestimates both event rates and the absolute benefit we see in real life. The COAST data are rightly included but adjusted down to a lower baseline admission rate, which again flattens the potential gain. In our experience, these patients are some of the most unwell and have frequent admissions, so the benefit of early haemodynamic feedback is much clearer than the model suggests. Finally, the improvement in quality of life is cut off after 12 months. From what we see in the clinic, that uplift absolutely persists if patients stay engaged with monitoring. So yes, the studies are covered — but the modelling feels a bit too conservative and doesn't quite capture the true "CardioMEMS-type" patient we look after at a tertiary centre.	hospitalisation rate, which is taken from the COAST UK study and includes only patients from NYHA class III. We found a calculation error which when corrected gives a baseline heart failure hospitalisation rate for Stable HF1 of 1.19. This is still less than the 1.52 rate reported in COAST UK because the rate from COAST UK is an average over patients who are in the Stable HF1, Stable HF2, Stable HF3, and Stable HF4 states. Because the heart failure hospitalisation rate increases depending on how many previous heart failure hospitalisations a patient has had, the rate in Stable HF1 will be lower than a weighted average across all the Stable HF states. The EAG adjusted the rate from COAST UK to account for this. We have provided our updated base-case results with the correction to the baseline heart failure hospitalisation and mortality rates. The EAG also provided results using the raw heart failure hospitalisation rate of 1.52 from COAST UK for comparison. To demonstrate the implications of the assumptions for Stable HF1, the EAG plotted the implied annualised heart failure hospitalisation rate for all patients alive under routine monitoring calculated in the model (1.19 and 1.52 for Stable HF1 respectively). This shows that by 12 months the

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				annualised hazard from the EAG base-case model is aligned with the rate from COAST-UK. The rate increases over time as patients progress to model states with higher heart failure hospitalisation rates. When using the raw rate of 1.52 from COAST-UK the heart failure hospitalisation rates are much higher. See the addendum for further details. Regarding utilities, the updated EAG base-case reflects the committee preference for Scenario 6c which applies the utilities from the MONITOR HF clinical trial for the first 12 months. The utility benefits are extrapolated beyond 12 months using the state-based utility approach in the absence of long-term health-related quality of life data. Therefore, there is a health-related quality of life advantage to CardioMEMS beyond 12 months due to fewer hospitalisations experienced in the monitoring group because utilities decrease with the number of heart failure hospitalisations a patient has. The EAG believe the state-based approach which uses the impactful drivers of health-related quality of life (hospitalisation and the resulting changes in health state) to be the best

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				way to extrapolate the long-term utilities in the absence of any data.
85	Consultee 6 Barts Health NHS Trust	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	The projected number of eligible patients per hospital also feels high compared with what most of us are seeing in the early adopter phase; it's more likely to be single or low double figures per year, not 50+. That makes a big difference when you model staffing and overheads. So while the summaries capture the right message, the magnitude of both benefit and cost feels skewed, the benefit understated, and the workload overstated.	Thank you for your comment. Please see response to comment 17.
86	Consultee 7 Individual	Not specified	There is reasonable evidence to support the improvement in quality of life which is not included in the model.	Thank you for your comment. Quality of life data from MONITOR-HF has been included in the model.
87	Consultee 8 Swansea Bay University Health Board	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	No My comments refer to Cardiomems only The assumptions made regarding hospital visits may be incorrect. I would expect that having a device would reduce the number of face to face visits, and reduce the number of overall visits. The time estimates and the frequency of measurements may not be appropriate in many patient groups and economies of scale would have a large impact. Having a band 5 nurse look at 10 monitors does not take 10 times the times it takes to look at one.	Thank you for your comment. Please see responses to comments 28, 47 and 48.
88	Consultee 13 Abbott Medical	1	Due to limitations of the online commenting submission process, Abbott are unfortunately unable to submit our health economic model directly. However, we have outlined below the key components and outcomes of our modelling.	Thank you for your comment. Although the EAG has not seen the company model it notes: -Utilities: the company's assumption is in line with the committee's preferences

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			Importantly, the model structure and baseline inputs remain consistent with the EAG model and the only modifications made were to reflect the committee's "preferred model assumptions.". To operationalise these changes, Abbott undertook the following: - Utilities: In line with the recommendation to adopt the approach used in scenario 6c (using utilities from MONITOR-HF for the first 12 months and health-state-based utilities thereafter) we implemented this exactly as described. - Monitoring Costs (Section 3.22): To reflect the committee's plausible monitoring schedule, we calculated the cost of a single 10-minute monitoring episode and adjusted it by multiplying the base cost by 147%, accounting for the higher salary of Band 7 nurses compared to Band 5. We interpreted "heart failure worsens" as equivalent to a heart failure hospitalisation event and added therefore £34.50 (cost of 3 monitoring sessions) to each hospitalisation in the CardioMEMS group to reflect additional monitoring post-discharge. For stable months, we applied a cost of £3.83 per month, assuming one monitoring episode every three months. - Prescribing Capability: To reflect the requirement that monitoring be conducted by a healthcare professional able to prescribe medication in response to PAP changes, we again applied the 147% multiplier to monitoring costs to account for Band 7 nurse salaries. Based on these updated inputs, our model yields an	and the EAG updated model. -Monitoring Costs: The company assume that intensification leads to 1 month at the higher monitoring frequency, followed by resuming to monitoring once every 3 months as for stable patients. Whilst these assumptions are in line with the statement of the committee's preferences in the draft guidance, they differ from the monitoring assumptions that were agreed between the EAG and NICE after further discussions with the clinical expert members of the committee. As can be seen by the difference between the results from the company's and EAG's models, cost-effectiveness results are very sensitive to assumptions around monitoring frequency, and so this is a key uncertainty that was discussed at committee. Please see responses to comment 63 and 68. The EAG provided results from a scenario where intensification occurs following hospitalisation in the addendum. -Prescribing Capability: the company have increased the cost to a Band 7 nurse who can prescribe. The EAG's

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			ICER of £16,649 per QALY and demonstrates a 68.1% probability of being cost-effective at a £20,000 per QALY threshold (graphs sent separately).	updated model also updated to a Band 7 nurse who can prescribe using a unit cost of £67 taken directly from the Unit Costs of Health and Social Care 2024. This is very similar to the £69 per hour assumed by the company.
89	Consultee 13 Abbott Medical	1	Abbott acknowledges that several of our initial concerns were addressed during the first committee meeting, which led to the development of the committee's "preferred model assumptions" as outlined in the draft guidance. However, we do not believe that the resulting updated model accurately reflects these assumptions, and therefore does not provide a true representation of their impact on the device's cost-effectiveness / ICER (as further detailed in our comment on section 3.18). To support a fair and evidence-based decision on cost-effectiveness, Abbott recommends that the committee be provided with an updated and accurate model that fully incorporates the preferred assumptions ahead of the next committee meeting.	Thank you for your comment. The final model which captures these assumptions has been provided.
90	Consultee 13 Abbott Medical	1.2 Should not be used	"CardioMEMS HF System (from here, CardioMEMS) should not be used for remote monitoring of chronic heart failure in adults." Abbott respectfully disagrees with this conclusion and believes it stems from inaccuracies within the EAG health economic model. We maintain that there is sufficient evidence to support the cost-effectiveness of CardioMEMS for remote monitoring of chronic heart failure in adults. This position is supported by the model we developed (aligned with the committee's "preferred model assumptions" as published in the draft guidance) which demonstrates an ICER of	Thank you for your comment. The recommendation has changed following the committee's consideration of the final model.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			£16,649 per QALY and a 68.1% probability of being cost-effective at a £20,000 per QALY threshold. In light of this, Abbott recommends that the guidance be amended to state: “1.1 CardioMEMS HF System (from here, CardioMEMS) can be used as an option for remote monitoring of chronic heart failure in adults.”	
91	Consultee 13 Abbott Medical	1.2 Should not be used	“Should not be used CardioMEMS does not offer value for money and should not be used in the NHS.” Abbott respectfully disagrees with this statement and believes the conclusion has been influenced by inaccuracies within the EAG health economic model. We are confident that sufficient evidence supports the cost-effectiveness of CardioMEMS for remote monitoring of chronic heart failure in adults. This is demonstrated by the model we developed and shared, which incorporates the committee’s "preferred model assumptions" as outlined in the draft guidance. The model yields an ICER of £16,649 per QALY and shows a 68.1% probability of being cost-effective at a £20,000 per QALY threshold. Based on this evidence, Abbott recommends that this should read "There is enough evidence to show that CardioMEMS provides benefits and value for money, so it should be used routinely across the NHS, and paid for using core NHS funding."	Thank you for your comment. The recommendation has changed following the committee’s consideration of the final model.
92	Consultee 13 Abbott Medical	3.14 Model design	"People with NYHA class 3 heart failure entered the model in a stable state, reflecting the health state for people whose condition has stabilised following an index admission." Abbott questions the accuracy of this statement, as the	Thank you for your comment. See response to comment 71. Lahoz data was used to inform the hazard ratios for those with 1, 2, or 3 previous recurrent heart failure hospitalisations relative to

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			EAG model uses data from Lahoz et al. (2020) to estimate the probability of heart failure hospitalisations and mortality without accounting for the NYHA classification of the patient cohort. As a result, we suggest revising the statement to: "People with heart failure (NYHA class not considered) entered the model in a stable state." This wording better reflects the uncertainty introduced by extrapolating data from a different patient population than that indicated for pulmonary artery pressure (PAP) monitoring.	the hazard ratio for heart failure hospitalisations for those with no recurrent heart failure hospitalisation (i.e. those in state Stable HF1). It was not used directly to inform the baseline heart failure hospitalisation or mortality rates in Stable HF1 itself. The baseline heart failure hospitalisation rate was based on COAST UK, and mortality rates were based on Griffiths et al 2024, both of which were on NYHA Class III patients. Lahoz was only used to adjust for patients who had multiple recurrent heart failure hospitalisation events. See the addendum for further details. All relative effects and other inputs for CardioMEMS were based on RCTs of patients who were NYHA Class III. The model is therefore designed to represent the NYHA Class III patient population.
93	Consultee 13 Abbott Medical	3.16 Heart failure hospitalisation rates	"The Lahoz et al. (2020) study reported data from 8,603 people with heart failure who had already had an index heart failure hospitalisation from the UK Clinical Practice Research Datalink." Abbott would like to clarify that Lahoz et al. (2020) includes all patients with a heart failure diagnosis and a prior hospitalisation recorded in primary care, representing a broader and more heterogeneous population than the specific cohort indicated for CardioMEMS (NYHA Class III patients with a heart failure hospitalisation in the previous 12 months).	Thank you for your comment. Please see comment 71. The EAG acknowledge that the Lahoz data may be from a broader population who are less symptomatic or clinically severe. However, as explained in the addendum the impact of the Lahoz data being a less severe population would be that it underestimates the proportion of patients with more recurrent heart failure hospitalisation events, and under-

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			As NYHA classification is not considered in Lahoz et al. (2020), the study likely includes patients who are less symptomatic or clinically severe than the target population for CardioMEMS. Consequently, the extrapolated baseline risks for hospitalisation and mortality may be underestimated, which in turn could lead to an underestimation of the potential benefit of pulmonary artery pressure (PAP) monitoring in the appropriate patient group. Abbott believes that to accurately reflect the potential benefit of PAP monitoring, the model baseline should be based on the patient cohort eligible for such intervention. Abbott acknowledges that data specific to this cohort may be limited, and therefore recommends that this limitation be taken into account when assessing the certainty and robustness of the model outcomes.	estimate the hazard ratios for those with more recurrent heart failure hospitalisations relative to Stable HF1 in COAST. This in turn would lead to a lower baseline heart failure hospitalisation rate in the Stable HF1 state from COAST UK when number of recurrent heart failure hospitalisations are adjusted for. The EAG did however find an error in our calculations which meant the value we used was too low. this was corrected, results in the addendum. The EAG agrees that there is limited information in the NYHA class III population on the hazard ratios for those with 1, 2, or 3 previous recurrent heart failure hospitalisations relative to the hazard ration for heart failure hospitalisations for those with no recurrent heart failure hospitalisation, and the Lahoz study was the most relevant evidence that we could find. For baseline heart failure hospitalisation rate there is evidence from COAST UK for the NYHA class III population, and this is used in the EAG model. Please see the addendum for further details.
94	Consultee 13 Abbott Medical	3.16 Heart failure hospitalisation	“The EAG used data from COAST to estimate the recurrent heart failure hospitalisation rate in the first	Thank you for your comment. Please see response to comment 71. The EAG

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		rates	stable heart failure state in the Markov model." Abbott believes that the baseline heart failure hospitalisation (HFH) rate used for the Stable HF1 state (0.8582) is too low for the relevant patient cohort and does not reflect real-world clinical practice. As referenced on page 115 of the EAR, patients in the UK-based COAST study experienced an average of 1.52 hospitalisations prior to receiving a CardioMEMS implant, nearly double the rate used in the current model. Given that the model extrapolates this rate downward (from 1.52 to 0.85) and distributes it across other hospitalisation states, Abbott would like to highlight that this approach likely underestimates the baseline risk of the initial hospitalisation and mortality. As a result, the potential benefit of pulmonary artery pressure (PAP) monitoring may also be underestimated. Abbott recommends that the baseline HFH rate for Stable HF1 should not be adjusted downward to assume the implant occurs post-index hospitalisation, as this does not reflect real-world practice. Instead, the model should reflect the actual number of hospitalisations typically experienced prior to CardioMEMS implantation.	found a calculation error which when corrected gives a baseline heart failure hospitalisation rate for Stable HF1 of 1.19. This is still less than the 1.52 rate reported in COAST UK because the rate from COAST UK is an average over patients who are in the Stable HF1, Stable HF2, Stable HF3, and Stable HF4 states. Because the heart failure hospitalisation rate increases depending on how many previous heart failure hospitalisation s a patient has had, the rate in Stable HF1 will be lower than a weighted average across all the Stable HF states. We therefore adjusted the rate from COAST UK to account for this. To do that the EAG used the Lahoz estimates of the hazard ratios and proportional split between the Stable HF states. The EAG did not use Lahoz to directly estimate the baseline heart failure hospitalisation rate in Stable HF1. As the company notes Lahoz may be a less severe population, and so these hazard ratios may be underestimated, and there may have been a higher proportion in Stable HF1 than would be seen in a NYHA Class II population. The impact of this when used to adjust the COAST-UK rates would be to over-estimate the baseline heart failure hospitalisation rate in Stable HF1

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
				The EAG provided updated base-case results with the correction to the baseline heart failure hospitalisation and mortality rates. It also provided results using the raw heart failure hospitalisation rate of 1.52 from COAST UK for comparison. To demonstrate the implications of the assumptions for Stable HF1, the EAG plotted the implied annualised heart failure hospitalisation rate for all patients alive under routine monitoring calculated in the model when 1.19 and 1.52 are used for Stable HF1 respectively. This shows that by 12 months the annualised hazard from the EAG base-case model is aligned with the rate from COAST-UK. The rate increases over time as patients progress to model states with higher heart failure hospitalisation rates. When using the raw rate of 1.52 from COAST-UK the heart failure hospitalisation rates are much higher. See the addendum for further details.
95	Consultee 13 Abbott Medical	3.16 Heart failure hospitalisation rates	"So, the committee concluded that it was possible that heart failure hospitalisation rate may have been underestimated or overestimated. But it also noted that this was uncertain based on the data available." Abbott agrees that there is uncertainty in the model and believes the baseline heart failure hospitalisation (HFH) rate has been underestimated. We therefore recommend that this uncertainty be carefully	Thank you for your comment. See previous responses to comment 71.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			considered when drawing firm conclusions about cost-effectiveness.	
96	Consultee 13 Abbott Medical	3.18 Healthcare professional costs	"The committee thought that adjusting the monitoring costs in the model would be unlikely to reduce the ICER sufficiently for CardioMEMS to fall within the range that NICE considers a cost-effective use of NHS resources." Abbott believes that assumptions regarding cost-effectiveness should not be made without re-running the model using the committee's "appropriate monitoring schedule.". As previously noted, when Abbott applied this schedule in our own modelling, the resulting ICER was £16,649 per QALY, with a 68.1% probability of being cost-effective at a £20,000 per QALY threshold. Below is a summary of the inputs and outcomes from our model, which retained the structure and baseline parameters of the EAG model, with modifications only to reflect the committee's "preferred model assumptions": - Utilities: In line with Scenario 6c, we applied utilities from MONITOR-HF for the first 12 months, followed by health-state-based utilities for the extrapolated period beyond 12 months. - Monitoring Costs (Section 3.22): We calculated the cost of a single 10-minute monitoring episode by a Band 7 nurse as £11.50 and we interpreted "heart failure worsens" as equivalent to a hospitalisation event. Accordingly, we added £34.50 (cost of 3 monitoring sessions) to each hospitalisation in the CardioMEMS group to reflect additional monitoring	Thank you for your comment. See response to comment 63.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			post-discharge. For stable months, we applied a cost of £3.83 per month, assuming one monitoring session every three months. - Prescribing Capability: To reflect the requirement for monitoring by a healthcare professional able to prescribe medication, we applied a 147% multiplier to monitoring costs to account for the higher salary of Band 7 nurses compared to Band 5.	
97	Consultee 13 Abbott Medical	3.19 The cost effectiveness of CardioMEMS	“The committee concluded that, given the cost of CardioMEMS, accounting for these uncertainties in the model would be insufficient to make it cost effective.” Abbott does not believe this assumption should be made without first re-running the model using the committee’s “appropriate monitoring schedule”. While we agree that uncertainty alone does not establish cost-effectiveness, incorporating the committee’s preferred model assumptions (specifically, a realistic CardioMEMS monitoring schedule and the utility values from Scenario 6c), does result in a cost-effective outcome.	Thank you for your comment. The final model has been provided and considered by the committee, and the recommendation has been changed.
98	Consultee 13 Abbott Medica	3.20 The cost effectiveness of Cordella	"The ICER for Cordella could not be estimated because its cost was unknown." Abbott agrees with this point but would also like to highlight that, even with a defined price, the ICER for Cordella could not be estimated due to inconclusive device-specific evidence.	Thank you for your comment. Section 3.20 has been amended to: The ICER for Cordella could not be estimated because its cost was unknown and clinical effectiveness evidence is inconclusive.
99	Consultee 13 Abbott Medical	3.21 Preferred model assumptions for this evaluation	"• use the cost of monitoring based on the salary for a healthcare professional who can prescribe medication when needed, in response to changes in PAP measurement."	Thank you for your comment. The change of band 5 to band 7 for the healthcare professional responsible for the monitoring has been changed in the

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			Abbott has taken this into account in our own modelling. To reflect the cost of monitoring by a healthcare professional qualified to prescribe medication in response to changes in PAP measurements, we applied a 147% uplift to the base monitoring cost, representing the salary difference between Band 7 and Band 5 nurses. Using these updated costs and utility values, our model produces an ICER of £16,649 per QALY and shows a 68.1% probability of being cost-effective at a £20,000 per QALY threshold.	EAG's model.
100	Consultee 14 Individual	1.2 Why the committee made these recommendations	There are a large number of assumptions in the modelling of the cost-effectiveness of CardioMEMS. The statement "results from the economic modelling of CardioMEMS show that it is not cost effective" imply a degree of confidence in the estimates that is not justified.	Thank you for your comment. The uncertainties in the final model are described in section 3.19 of the guidance.
101	Consultee 15 British Cardiovascular Society	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	2. The cost efficacy models provided overestimate the time required to optimise a patient and probably underestimate the recurrent rate of admissions. Again these factors need to be entered into a revised economic modelling.	Thank you for your comment. Please see response to comment 94 regarding recurrent heart failure hospitalisation rate. The committee discussed uncertainties in the model, these are described in section 3.19 of the guidance.

Theme 5 – Procedure and safety

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
102	Consultee 13	3.12 Safety	"The clinical experts explained that failure after	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
	Abbott Medical		implantation was rare and that, when implantation failure happens, it does not lead to products being discarded. The committee concluded that the technologies are safe to use and have an acceptable failure rate." Abbott strongly agree with this statement and the committee's conclusion.	
103	Consultee 8 Swansea Bay University Health Board	Are the recommendations sound and a suitable basis for guidance to the NHS?	No! There are errors in the draft guidance regarding cardiomems which would influence its cost effectiveness 1) The device does not require a general anaesthetic for implantation. This substantially reduces its cost and improves cost effectiveness	Thank you for your comment. We have corrected the final guidance to remove reference to general anaesthesia. The EAG noted that general anaesthetic was not included in the model so no changes were needed to the model.
104	Consultee 15 British Cardiovascular Society	Are the summaries of clinical and resource savings reasonable interpretations of the evidence?	1. The assertion that CardioMEMS implant needs be performed under general anaesthesia is factually inaccurate. Having consulted experts that implant these devices, procedures are almost exclusively performed as a day-case procedure with venous access from the neck and with most patients able to be safely discharged within a few hours. This assumption needs to be factored into a revised economic modelling.	Thank you for your comment. Please see response to comment 103.
105	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations	Cardiomems is NOT a general aneasthetic procedure	Thank you for your comment. Please see response to comment 103.
106	Consultee 1 University Hospital Southampton	1.2 Why the committee made these recommendations	This is a ridiculous statement, this procedure is done under local anaesthetic, sometimes with sedation. There is absolutely no requirement for a general anaesthetic	Thank you for your comment. Please see response to comment 103.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
	NHS Trust	Selected text: *that some people might not be able or willing to have a general anaesthetic, which is needed for this procedure*		
theme107	Consultee 1 University Hospital Southampton NHS Trust	3.13 Patient selection Selected text: *having a general anaesthetic and a right heart catheterisation procedure*	There is absolutely no requirement for general anaesthetic.	Thank you for your comment. Please see response to comment 103.
108	Consultee 13 Abbott Medical	1.2 Why the committee made these recommendations	"• that some people might not be able or willing to have a general anaesthetic, which is needed for this procedure" Abbott would like to clarify that this statement is inaccurate, as the procedure does not require general anaesthesia. Only local anaesthesia is used.	Thank you for your comment. Please see response to comment 103.
109	Consultee 13 Abbott Medical	3.13 Patient selection	"• having a general anaesthetic and a right heart catheterisation procedure" Abbott would like to clarify that this statement is inaccurate, as the procedure does not require general anaesthesia. Only local anaesthesia is used.	Thank you for your comment. Please see response to comment 103.

Theme 6 – Equality and access

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE responses/EAG considerations
110	Consultee 5 Leeds Teaching Hospitals NHS Trust	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	No	Thank you for your comment.
111	Consultee 7 Individual	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	.No answer text	Thank you for your comment.
112	Consultee 9 Individual	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	None additional to those that have been expressed previously.	Thank you for your comment.
113	Consultee 15 British Cardiovascular Society	Are there any equality issues that need special consideration and	None.	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE responses/EAG considerations
		are not covered in the medical technology consultation document?		
114	Consultee 6 Barts Health NHS Trust	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	Yes - several, and they're important. Geography: If this is commissioned only in a few large centres, we risk widening the gap between regions. Patients living far from tertiary hospitals are often the ones who'd benefit most from fewer hospital visits and more remote oversight. Socioeconomic deprivation: We see higher heart failure burdens in deprived areas. These patients have more admissions but also face barriers to attending follow-up. CardioMEMS could reduce those pressures, but only if access isn't limited by postcode or funding geography. Digital exclusion: Not everyone is tech-savvy or has reliable internet or phone access. We have to design services that can support patients who struggle with technology, including translated materials and carer support. Otherwise, we'll end up serving a narrower, more advantaged population. Younger and congenital heart disease patients: These groups are rarely represented in the models but are often among the most motivated and engaged, and they can gain hugely in terms of	Thank you for your comment. The committee changed the recommendation for CardioMEMS to a positive recommendation based on the results of the final model. As part of decision-making, the committee discussed equalities issues and recognised the potential of the technology to reduce health inequalities.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE responses/EAG considerations
			stability and quality of life. They shouldn't be unintentionally excluded just because they don't fit the "average" heart failure profile. Disability and caring responsibilities: For people who find frequent hospital visits physically difficult or who care for others, avoiding unplanned admissions is especially valuable. That equity impact deserves explicit mention. So in short, while the technology itself could reduce inequalities if rolled out thoughtfully, the current structure of the guidance might inadvertently widen them. I'd encourage NICE to recognise that and to make equity a core part of how local implementation is designed.	
115	Consultee 8 Swansea Bay University Health Board	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	Yes This device would support care of disadvantaged patients in remote regions such as West Wales where patients with heart failure might need to travel 120 miles to visit their cardiac centre. This is particularly true if there are additional transport issues or disability.	Thank you for your comment.
116	Consultee 10 Edwards Lifesciences	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	No, all equality issues have been covered in the document	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE responses/EAG considerations
117	Consultee 11 Heart Failure Warriors NI	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	To avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation, we believe you need to include everyone and avoid post code lottery based on where people live. Everyone should have equal access to technologies designed to help monitor their HF and keep them out of hospital.	Thank you for your comment.
118	Consultee 14 Individual	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	Implantable PA pressure sensors may reduce geographical inequity of access to advanced heart failure care because patients who are waiting for heart transplantation but live a long way from their transplant centre are more easily able to receive surveillance.	Thank you for your comment. The committee recognised the potential for remote PAP monitoring technologies to reduce inequality of access to heart failure services for people living in geographically remote areas. Please see section 3.22 of the guidance and the equality impact assessment.
119	Consultee 1 University Hospital Southampton NHS Trust	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	People in rural areas or island communities stand more to benefit from remote monitoring	Thank you for your comment. Please see response to comment 118.
120	Consultee 2 British Society for Heart Failure	Are there any equality issues that need special consideration and are not covered in the medical	Remote monitoring is regarded as a critical intervention to mitigate disparities in healthcare access between patients residing in rural areas, who often face significant geographic barriers to hospital services, and those in urban settings with proximity to healthcare facilities.	Thank you for your comment. Please see response to comment 118.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE responses/EAG considerations
		technology consultation document?	Comment by [redacted]	
121	Consultee 4 University Hospitals Dorset	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	I have not identified specific equality issues beyond those already described. However, I would note that equitable access to PAP monitoring could help reduce inequalities in heart failure care — particularly for patients in remote or underserved areas who would otherwise have limited access to specialist teams.	Thank you for your comment. Please see response to comment 118.
122	Consultee 8 Swansea Bay University Health Board	Are the recommendations sound and a suitable basis for guidance to the NHS?	3) There may be high risk patients who may benefit more from the device - e.g. those with multiple admissions, those living a long way from their centre, those with disability and immobility, and those who decompensate quickly with little warning. I would strongly favour making the device available for a small number of high risk patients in tertiary or quaternary heart failure units following MDT agreement. NICE should recommend implementation studies in these high risk groups. The company could also consider making the PAP measurements available to patients via an App which would then make the device more cost effective in that selected patents could monitor themselves without the need for hospital input.	Thank you for your comment. The committee changed the recommendation for CardioMEMS to a positive recommendation based on the results of the final model. CardioMEMS does have an app for patient use called myCardioMEMS.
123	Consultee 13 Abbott Medical	Are there any equality issues that need special consideration and are not covered in the medical	Remote monitoring is recognised as a key strategy for reducing healthcare access disparities, particularly between patients in rural areas, who often encounter significant geographic barriers to hospital services, and those in urban settings with easier access to healthcare facilities.	Thank you for your comment. Please see response to comment 118.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE responses/EAG considerations
		technology consultation document?		
124	Consultee 13 Abbott Medical	1	Abbott views remote monitoring as a key strategy to help reduce disparities in access to care between patients living in rural areas, who may face significant travel barriers to hospital services, and those in urban areas with easier access to healthcare facilities.	Thank you for your comment. Please see response to comment 118.

Theme 7 – Other

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
125	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations	Our experience is that the technology is that it is easy to use and carers also find it very helpful.	Thank you for your comment.
126	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations Selected	All feedback from patients say the technology is easy for them to use, confirmed by the very high percentage of daily readings in our population	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		text: *how easy the technology is to use for the person with the condition and their carers.*		
127	Consultee 1 University Hospital Southampton NHS Trust	2.3 2 Information about the technologies Selected text: *The aim is not to replace any aspects of this monitoring, nor to make or confirm diagnosis of heart*	I think this is incorrect. In our 2 year FU data interactions with the HF team were similar in the year before implant and the year post implant (which included optimisation phase). In the second year of FU interactions with HF team were dramatically reduced due to the patients being stable. (Year prior 148 interactions, 1 year post 147 interactions, year 2, 40 interactions). Occasional intervention responding to abnormal trends takes much less time remotely than seeing patients regularly F2F.	Thank you for your comment. Please see response to comment 28.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		failure.		
128	Consultee 1 University Hospital Southampton NHS Trust	3.7 CardioMEMS Selected text: *contemporary treatment of chronic heart failure has changed since the earlier trials were done*	The main benefit of CardioMEMS is the focus on treating congestion. Changing diuretic dose is the most common drug change. This has not changed since the trials were done	Thank you for your comment. The intention of this text was to highlight that in the more recent trials, medicines optimisation for people with heart failure might be better than it was in the past.
129	Consultee 1 University Hospital Southampton NHS Trust	3.13 Patient selection Selected text: *The clinical experts said that people generally*	Our patients strongly express reassurance from this technology and some of the more motivated patients adjust their medication according to the changes in pulmonary artery diastolic pressure readings without interaction with the clinical team. No patient has expressed discomfort at the thought of having an implantable device. Patients are of course free to decline the technology if they wish	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		feel comfortable living with an implanted sensor and some people may feel reassured by knowing that their heart failure is being continuously monitored. But other people could feel uncomfortable with having a sensor implanted, living with it		

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		and find the monitoring requirements to be a burden. The person's ability to adhere to using the technology and medication changes, and their comfort with living with the implanted sensor, would need to be considered as part of shared		

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		decision-making.		
130	Consultee 1 University Hospital Southampton NHS Trust	1.2 Why the committee made these recommendations	our experience of 30 patients with cardiomems is excellent adherence and compliance with monitoring schedule and changes to medication	Thank you for your comment.
131	Consultee 3 Individual	Has all of the relevant evidence been taken into account?	NO As a dedicated caregiver for my husband, who has been living with heart failure for a decade and benefiting from the CardioMEMS implant, I am a passionate advocate for its widespread adoption within the NHS. Witnessing the positive impact of this innovative device firsthand, including reduced hospitalisations and improved quality of life, has fuelled my support to ensuring all eligible patients have access to this wonderful technology. We certainly recognise CardioMEMS system, to be an essential piece of technology to enhance proactive care, improve patient outcomes, and ultimately transform the management of heart failure within the NHS. Since my husband has had this device fitted we can see huge benefits for all patients with heart failure. Not only doe this give you exceptional health benefits is also gives you the piece of mind that a healthcare professional is monitoring the device readings daily. We feel there are many positive benefits to this devis in which I have list a few below: * Reduced Hospitalisations: Fewer hospital readmissions due to better heart failure management, cutting down on expensive	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			hospital stays. * Improved Quality of Life: Continuous monitoring allows proactive adjustments to medications and treatments, leading to patients feeling better and being more active. * Early Detection of Problems: Detects changes in pulmonary artery pressure early, enabling timely interventions and preventing serious health crises. * Remote Monitoring: Convenient at-home monitoring reduces the need for frequent hospital visits. * Patients are more likely to stick to treatment plans due to visible impact through monitoring data. * No General Anaesthetic Needed: The implantation procedure doesn't require general anaesthetic, reducing risks and recovery time and hospital stays. * No additional GP appointments are needed as patients can go directly to the hospital to communicate their readings. * Total Peace of Mind: Continuous monitoring provides patients and caregivers with peace of mind, knowing that any issues will be detected and addressed promptly. This peace of mind is invaluable and worth the investment. * Cost-Effectiveness – There would be no A&E visits, no 4 to 5 days on a ward, no procedure to drain the fluid, no bed blocking when not needed and the general burden on the NHS healthcare.	

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
132	Consultee 5 Leeds Teaching Hospitals NHS Trust	3.19 The cost effectiveness of CardioMEMS	This estimate does not reflect real world experience. In COAST no site recruited more than 12 patients per annum when fully established - average 2.45 patients per year (range 0.33 - 6.33). In addition, when UK data are used to estimate a potential patient group and takes into account, NYHA III symptoms, established on GDMT and frailty an estimate of the PAP monitoring patient population ranges between 770-2200 patients per annum. In our cohort of patients I believe implant rates would be a maximum of 10-12 patients per year.	Thank you for your comment. The EAG model is for an individual patient who is eligible for implantation, and as such does not depend on the volume of patients who would be eligible. The EAG base-case did not include a cost for the calibration unit but did run a scenario where the estimated the cost of the calibration unit per patient. To do that the EAG did use an estimated volume of 56 patients per year per calibration unit to get a rough approximate price for this. If the volume were lower at 10-12 patients per year, then the estimated per patient cost for the calibration unit would be approximately 5 times higher than in the scenario. However, the impact of the cost of the calibration unit was negligible, and so although increasing the per patient cost would increase the ICER, the EAG do not expect this would have a notable impact on the ICER.
133	Consultee 8 Swansea Bay University Health Board	Are the recommendations sound and a suitable basis for guidance to the	2) Non-adherence to the monitoring schedule is unlikely to be an issue. A strict schedule may not be appropriate for some patients.	Thank you for your comment.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
		NHS?		
134	Consultee 13 Abbott Medical	1	[redacted]	Thank you for your comment.
135	Consultee 13 Abbott Medical	1.2 Why the committee made these recommendations	"• non-adherence to the monitoring schedule and changes to medication" Abbott would like to clarify that this statement is not supported by any available data.	Thank you for your comment. Please see section 5.5.2.6 of the EAG report provides trial data on adherence to using the device.
136	Consultee 15 British Cardiovascular Society	Are the recommendations sound and a suitable basis for guidance to the NHS?	1. The "should not be used" recommendation for CardioMEMS is in our opinion too strongly worded and may be seen by clinicians/hospitals as prohibiting the appropriate use of the device, even in settings where the cost is not (fully) imposed on the NHS, e.g. research settings. We would recommend re-wording this statement to "could be used as agreed by consensus following a multidisciplinary team discussion" as a more reasonable alternative. 2. There is some evidence for benefit in reducing HF hospitalisation but uncertainty as to how to select the most appropriate patients and also how the monitoring is going to be	Thank you for your comment. The committee changed the recommendation for CardioMEMS to a positive recommendation based on the results of the final model (please see the addendum for further details). Please also see response to comment 118 in regarding geographical location.

Comment Number	Consultee number/ organisation name	Section number	Comment	NICE Response/EAG considerations
			managed within our current HF services. While it is unlikely that pulmonary artery pressure monitors will be part of standard heart failure management for all patients with heart failure in the UK for all patients the foreseeable future, our view is that there are subgroups of patients with advanced heart failure (for example, those being considered for listing for heart transplantation), who already benefit from the use of these devices in a real-world setting. 3. Patients being managed under tertiary or quaternary services often have to travel long distances for face-to-face clinical assessment and the use of these devices provides a very attractive option for remote continuous haemodynamic monitoring which allows care for patients to remain in the community. This is the very ethos of the current government's 10 year Health Plan which aims to see care shifted "from the hospital to the community to deliver an NHS fit for the future". For these reasons, we think it is imperative that the views from physicians working in cardiac transplant centres and those patients being managed under such centres should be taken into account. In summary, it is our opinion that the NICE guidance needs to reflect the fact that there are likely to be groups of advanced heart failure patients where implantable PA pressure monitors are cost effective. For those patients, acknowledging that the evidence base is limited and that performing adequately powered studies in these smaller cohorts is challenging, use of these devices should be deemed acceptable as guided by a multidisciplinary team.	

Cont/..

For the committee version of the collated comments table all data can remain and must be marked correctly for DPD and AIC, CIC.

In the collated comments version for publication, please ensure:

1. All consultee names are removed and replaced with i.e., Consultee 1, 2, 3 or Web comment or the organisation name who submitted the comment.
2. All Personal Data (PD) is removed or redacted from the comments.

- Please ensure all ACIC information is redacted.

This comments table may also be used at other points in the feedback process, e.g. collation of committee feedback on DG, or EAG feedback on DG, in these cases responses to comments do not require a formal response and the document will not be made publicly available and should not be circulated outside the Health Tech team. Any changes to the DG as a result of any of these comments, however, should be recorded in the far-right column.