NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Pulmonary artery pressure technologies for remote monitoring of chronic heart failure

Guidance development process

NICE diagnostics guidance evaluates diagnostic tests and technologies. It provides evidence-based recommendations about how accurate and effective the tests are, as well as their costs. The guidance supports healthcare professionals and commissioners to choose the best diagnostic options to improve patient care. NICE aims to enhance the quality of diagnostic practices in the UK, leading to better health outcomes for patients.

Find out more on the NICE webpage on the diagnostics assessment programme.

NICE is producing this guidance on pulmonary artery pressure technologies for remote monitoring of chronic heart failure in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?

- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we 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?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again, it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on pulmonary artery pressure technologies for remote monitoring of chronic heart failure. The recommendations in section 1 may change after consultation.

More details are available in NICE's health technology evaluations: the manual.

Key dates:

Closing date for comments: 11 November 2025

Second committee meeting: 18 November 2025

1 Recommendations

More research is needed

1.1 More research is needed on the Cordella Pulmonary Artery Sensor System and the Cordella Heart Failure System (from here, Cordella) for remote monitoring of chronic heart failure in adults before it can be funded by the NHS.

What research is needed

More research is needed on:

- the clinical effectiveness of the technology, including the impact on heart failure hospitalisations
- the short-term impact of the technology on quality of life
- defining which groups of people the technology is most suitable for.

Should not be used

1.2 CardioMEMS HF System (from here, CardioMEMS) should not be used for remote monitoring of chronic heart failure in adults.

What this means in practice

More research is needed

There is not enough evidence to support funding Cordella in the NHS.

Access to Cordella should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

Should not be used

CardioMEMS does not offer value for money and should not be used in the NHS.

Why the committee made these recommendations

Evidence from non-comparative studies suggests that Cordella may reduce heart failure hospitalisations but this needs confirming. There is some evidence from randomised controlled trials that CardioMEMS can reduce heart failure hospitalisations. But this is uncertain because the people included in the trials were younger than the people who would use the technology in the NHS. It is also uncertain whether using either technology affects how long people live, or their quality of life. There are no trials directly comparing CardioMEMS with Cordella. An indirect comparison suggests no difference in heart failure hospitalisations between the 2 technologies. But this is uncertain because of the data used in the comparison.

Ongoing monitoring could be reassuring for people with chronic heart failure and help to quickly identify any need for medication changes. Potential concerns about the technologies include:

- that some people might not be able or willing to have a general anaesthetic, which is needed for this procedure
- non-adherence to the monitoring schedule and changes to medication
- how easy the technology is to use for the person with the condition and their carers.

The technologies could reduce resource use in the NHS by reducing the number of heart failure hospitalisations. But, the cost effectiveness of Cordella cannot be established because its cost is unknown. Also, because there is limited evidence on its clinical effectiveness, it can only be used in research. Results from the economic modelling of CardioMEMS show that it is not cost effective. So, it should not be used.

2 Information about the technologies

2.1 Pulmonary artery pressure (PAP) monitoring systems use implantable sensors to collect data on PAP to remotely monitor chronic heart failure. The aim of PAP technologies is to detect increases in PAP at an early stage. PAP increases mean that fluid

is beginning to accumulate because of worsening heart failure. So, early detection increases the possibility of optimising medication, and avoiding decompensation of heart failure and hospitalisation.

2.2 A PAP sensor is implanted into a pulmonary artery using a right heart catheterisation procedure. NICE's interventional procedure guidance on percutaneous implantation of PAP sensors for monitoring treatment of chronic heart failure recommends that the evidence on safety and efficacy is adequate to support this procedure.

2.3 People take daily PAP measurements at home. Data, including on pressure trends and waveforms, is collected and transmitted to an external monitor in the home. The monitor securely forwards this information to a remote database that can be accessed by the person's healthcare team. The aim of PAP technologies is to supplement usual monitoring for chronic heart failure. The aim is not to replace any aspects of this monitoring, nor to make or confirm diagnosis of heart failure.

2.4 Two technologies were identified as relevant for inclusion in this evaluation:

- CardioMEMS HF System (from here, CardioMEMS)
- Cordella Pulmonary Artery Sensor System and Cordella Heart Failure System (from here, Cordella).

Table 1 Summary of pulmonary artery pressure monitoring technologies included in this evaluation

Technology	CardioMEMS HF System (from here, CardioMEMS; Abbott Medical)	Cordella Pulmonary Artery Sensor System and Cordella Heart Failure System (from here, Cordella; Endotronix/Edwards Life Sciences)
Intended use	CardioMEMS is indicated for wirelessly measuring and	Cordella is intended to measure, record and

	monitoring pulmonary artery pressure (PAP) and heart rate for people with chronic heart failure. In the UK, to have this technology, people need to have: • New York Heart Association (NYHA) class 3 symptoms, and • a prior hospitalisation for heart failure within the last 12 months, regardless of ejection fraction status.	transmit PAP data for people with NYHA class 3 heart failure who: • are at home on diuretics and guideline-directed medical therapy, and • have been stable for 30 days.
Contraindications	CardioMEMS is contraindicated for people who are unable to take dual antiplatelet therapy or anticoagulants following implantation.	Cordella is contraindicated for people who are unable to take dual antiplatelet therapy or anticoagulants following implantation.
CE mark status	Class 3 CE mark	Class 3 CE mark
Description	A small pressure sensor is permanently implanted in the distal pulmonary artery during a minimally invasive right heart catheterisation procedure. The sensor is secured with nitinol wire loops. It measures PAP changes, which reflect fluid retention in the lungs because of worsening chronic heart failure. At home, people use a portable electronics unit and a pillow with an embedded antenna. By lying down on the pillow and activating the technology, they take daily pressure readings by pressing a button. The data is sent wirelessly to a secure database for healthcare professionals to review. They can see trends and adjust medication and other treatments as needed, often before symptoms appear. This can potentially reduce the risk of decompensation of heart failure and hospitalisation.	A sensor is implanted in the pulmonary artery, and readings can be taken at home by holding a wireless handheld reader against the right pectoral region for 20 seconds. In addition to PAP data, this technology measures vital signs including blood pressure, heart rate, weight, and oxygen saturation. Collected data is sent to the myCordella Hub, which guides people on how to use the technology, asks health-related questions, and transmits information to the myCordella Patient Management Portal for healthcare professionals to access. This technology aims to assist healthcare professionals in assessing and managing heart failure, potentially reducing hospitalisations.

NHS use	In the NHS in England, CardioMEMS has mostly been used in a trial setting and is not routinely used.	Cordella is not currently used in the NHS.
Price	£9,500	Not provided

3 Committee discussion

The diagnostics advisory committee considered evidence on pulmonary artery pressure (PAP) technologies for remote monitoring of chronic heart failure from several sources. This included evidence submitted by Abbott and Endotronix/Edwards Life Sciences, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Heart failure is caused by any structural or functional cardiac condition that impairs the heart's ability to function efficiently and pump blood around the body. The most common symptoms of heart failure are breathlessness, fatigue and oedema. Heart failure may be classified by ejection fraction:

- heart failure with preserved ejection fraction (HFpEF; 50% and over)
- heart failure with mildly reduced ejection fraction (HFmrEF; between 40% and 49%)
- heart failure with reduced ejection fraction (HFrEF; below 40%).

Heart failure may also be classified by symptom severity and limitation of physical activity using the New York Heart Association (NYHA) classification system. This ranges from class 1 (no limitations) to class 4 (inability to carry out physical activity without discomfort and symptoms, which may be present at rest).

Current practice

3.2 NICE's guideline on diagnosing and managing chronic heart failure in adults recommends that monitoring of chronic heart failure should include:

- a clinical assessment of functional capacity, fluid status, cardiac rhythm, cognitive status and nutritional status
- a review of medication
- an assessment of renal function.

The European Society for Cardiology guideline on diagnosing and treating acute and chronic heart failure adds that heart failure management may involve in-person services or home-based telemonitoring. While care is usually followed up in heart failure clinics, people whose condition is suitable may be followed up by a range of healthcare professionals, including community heart failure nurses, GPs with a special interest in heart failure and specialist pharmacists. People should have additional monitoring if they have comorbidities, are taking coprescribed medications or if their condition has deteriorated since their last review. The frequency of monitoring depends on the clinical status and stability of the person's condition.

Unmet need

3.3 Heart failure accounts for 2% of all NHS inpatient bed days (a total of 1 million inpatient bed days each year) and 5% of all emergency medical admissions to hospital. The clinical experts said that heart failure is the most common reason that people over 60 years are admitted to hospital. Hospitalisations for heart failure can have an impact on the quality of life of people admitted with it and are a significant cost to the NHS. PAP monitoring technologies offer remote monitoring of chronic heart failure, the aim being to reduce hospitalisations for heart failure. The technologies would be used

as an add-on to usual clinical management of NYHA class 3 heart failure. The committee concluded that the technologies would need to be integrated into specialist multidisciplinary heart failure services, with alerts and trend data monitored and managed by specialist healthcare professionals.

Clinical effectiveness

Clinical evidence

3.4 The committee discussed the evidence base for this evaluation, which consisted of:

- 3 randomised controlled trials (RCTs) comparing CardioMEMS with usual care (CHAMPION, GUIDE-HF and MONITOR-HF)
- 3 single-arm prospective studies for CardioMEMS, included for device-related outcomes only (COAST, MEMS-UK and CardioMEMS-PAS)
- 2 studies on patient experience of CardioMEMS (Assaad et al. 2018 and Haynes et al. 2020)
- 3 prospective single-arm studies for Cordella (SIRONA, SIRONA 2 and PROACTIVE-HF).

  PROACTIVE-HF was originally designed as an RCT and changed to a single-arm study part way through. Some data from the randomised phase of PROACTIVE-HF was included in the evaluation. Two studies included patient survey results that contributed data on patient experience and satisfaction (PROACTIVE-HF and SIRONA 2).

Study size, quality and populations

3.5 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. There was a high proportion of men in the studies (for example, over 70% of people in CHAMPION were men). One of the clinical experts explained that there is no reason to believe that the technology would be less beneficial for women, trans and non-binary people.

The committee concluded that the study populations were less diverse than the real-world population of people with heart failure in terms of gender, age and ethnicity. 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.

Medication

3.6 One clinical expert explained that pharmacological management of chronic heart failure has changed since some of the studies were carried out, particularly for HFpEF. Previously, treatment for HFpEF relied on diuretics alone, but current practice includes mineralocorticoid receptor antagonists and sodium-glucose cotransporter 2 inhibitors in addition to diuretics. Most of the studies were done recently and reflect contemporary treatment of chronic heart failure. CHAMPION began enrolment in 2007 and reflected HFpEF treatment at the time. The committee concluded that this did not affect the interpretation of the results for this evaluation. This was because most people with HFpEF in the overall analysis of all the studies would have had treatment in line with contemporary treatment.

Heart failure hospitalisations

CardioMEMS

3.7 Evidence from 3 RCTs (CHAMPION, GUIDE-HF and MONITOR-HF) comparing the effect of CardioMEMS on heart

failure hospitalisations with usual care in people with NYHA class 3 heart failure was included in a meta-analysis. The results of the meta-analysis showed that CardioMEMS was associated with a reduction in heart failure hospitalisations compared with usual care, with high certainty in the evidence (summary hazard ratio [HR] 0.66, 95% confidence interval [CI] 0.57 to 0.76). The committee noted some limitations in the evidence, including:

- people in the trial were younger than the real-world UK chronic heart failure population
- contemporary treatment of chronic heart failure has changed since the earlier trials were done
- the largest trial, GUIDE-HF, included people with NYHA class 2 to 4 heart failure.

The primary analysis was restricted to the NYHA class 3 population. Data for the full trial population suggested an overall reduction in heart failure hospitalisation (HR 0.83, 95% CI 0.68 to 1.01). There was stronger evidence for a reduction in heart failure hospitalisations in the period before the COVID-19 pandemic (HR 0.72, 95% CI 0.57 to 0.92). But there was no statistically significant difference between the intervention and control group during the COVID-19 pandemic. This means that any reduction in heart failure hospitalisations seen in routine practice with CardioMEMS might not be as large as was reported in the trials. The committee concluded that there was some evidence to support a reduction in heart failure hospitalisations with CardioMEMS.

Cordella

3.8 Data supplied by the manufacturer of Cordella for the randomised phase of PROACTIVE-HF suggested a reduction in heart failure hospitalisations with Cordella. But the committee thought that this was uncertain because of the small number of people in the

randomised phase and some concerns about the risk of bias. The results of 2 of the non-comparative studies that evaluated Cordella suggested a reduction in heart failure hospitalisations. The committee concluded that the evidence was too uncertain to support that it reduced heart failure hospitalisations.

CardioMEMS compared with Cordella

3.9 An indirect comparison of CardioMEMS and Cordella was done using the evidence from the 3 RCTs of CardioMEMS and evidence from the RCT phase of PROACTIVE-HF. The results suggested no difference in heart failure hospitalisations between the 2 technologies. The committee noted that the comparator in PROACTIVE-HF differed from the comparator in the CardioMEMS trials, so this result was highly uncertain. 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

All-cause mortality

3.10 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. The RCT results suggested a small decrease in mortality with CardioMEMS. For Cordella, data provided by its manufacturer for the comparative phase of PROACTIVE-HF suggested a small decrease in all-cause mortality. Confidence intervals were wide and consistent with both an increased and decreased risk of death for CardioMEMS (HR 0.91, 95% CI 0.70 to 1.17) and for Cordella (HR 0.51, 95% CI 0.20 to 1.32). Indirect comparison of Cordella with CardioMEMS suggested no evidence of a difference in all-cause mortality between the 2 technologies. But the estimate was very imprecise. The

committee concluded that it was uncertain whether either technology reduced all-cause mortality from the evidence available.

Quality of life

3.11 All the studies provided data on health-related quality of life (HRQoL). This was measured using the EQ-5D-5L visual analogue scale, the Kansas City Cardiomyopathy Questionnaire (KCCQ) or the Minnesota Living with Heart Failure questionnaire. The impact of PAP monitoring technologies on HRQoL was mixed. For CardioMEMS, the studies had results in the opposite direction, so the findings were inconsistent. MONITOR-HF reported an increase in EQ-5D-5L score and GUIDE-HF reported a decrease. The summary estimate from the meta-analysis was a mean non-statistically significant increase in EQ-5D score of 1.75 EQ-5D (95% CI -6.03 to 9.53; a higher score is better). So, the summary estimate was of limited value. The overall result of the meta-analysis for the KCCQ was a mean non-statistically significant increase in KCCQ of 3.63 (95% CI -2.24 to 9.47; a higher score is better). For Cordella, data on HRQoL was limited and lacked direct comparisons, making it difficult to draw conclusions. The committee thought that the evidence for HRQoL and mortality was inconclusive for both technologies. It concluded that it was uncertain whether either technology improved HRQoL.

Safety

3.12 Data from the quantitative studies included in this evaluation showed that:

- Implantation failure was rare. Implantation of the technology failed in 1.7% of people (95% CI 0.8% to 2.9%) with CardioMEMS and in 4.9% people (95% CI 3.1% to 7.0%) with Cordella.
- Device or system, or procedure-related complications were rare. The summary proportion of these complications across trials

was 0.7% (95% CI 0.3 to 1.3%) with CardioMEMS and 0.1% (95% CI 0.0 to 0.09%) with Cordella.

- Data from all quantitative studies except GUIDE-HF showed that the proportion of people with a sensor implanted in whom the sensor subsequently failed was low (0 to 1.2% overall). The summary estimate was 0.1% (95% CI 0.0 to 0.6%) for CardioMEMS and 0% (95% CI 0.0 to 0.1%) for Cordella. GUIDE-HF did not report sensor failure.

The clinical experts explained that failure after 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.

Patient selection

3.13 To benefit from using a PAP technology, people need to be comfortable with:

- having a general anaesthetic and a right heart catheterisation procedure
- taking routine measurements at home
- acting on any changes to their medication that are needed because of PAP changes.

Qualitative data included in this evaluation suggested that people were positive about using the technologies and that the technologies improved their understanding of their condition. The clinical experts said that people generally 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 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 decision-making.

Other options for remote monitoring of chronic heart failure are available, including algorithm-based remote monitoring systems, which use data from cardiac implantable devices, and virtual wards. Patient selection would also need to consider which methods of remote monitoring are available and would be most suitable for the patient. The committee concluded that patient selection would need to be carefully considered.

Cost effectiveness

Model design

3.14 The EAG developed a multistate Markov model to estimate the cost effectiveness of remote PAP monitoring technologies compared with current monitoring practice (standard care). 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. The model consisted of 8 mutually exclusive states (stable heart failure 1, first recurrent heart failure hospitalisation, stable heart failure 2, second recurrent heart failure hospitalisation, stable heart failure 3, subsequent recurrent heart failure hospitalisation, stable heart failure 4, and death). The model used a cycle length of 1 month and a lifetime time horizon.

The key clinical input in the model was heart failure hospitalisation rates. In the model, the risk of having a subsequent heart failure hospitalisation increased with the number of previous heart failure hospitalisations. The effect of PAP monitoring was to reduce the rate of heart failure hospitalisations, and this effect was assumed to

continue regardless of how many previous heart failure hospitalisations a patient had had. The risk of death increased with each stable state, and the utility associated with each stable state declined as heart failure hospitalisations increase. The committee agreed that the design of the model was appropriate.

Impact of heart failure hospitalisations

3.15 The committee discussed the key drivers of the model. One way sensitivity analysis showed that the effectiveness of CardioMEMS at reducing heart failure hospitalisations had the largest impact on the incremental cost-effectiveness ratio (ICER). At the lower bound of the CardioMEMS hazard ratio, the ICER was reduced by over £17,000 per quality-adjusted life year (QALY). At the upper bound, the ICER was increased by over £40,000. All other variables included in the deterministic sensitivity analysis had a less than £10,000 impact on the ICER. The implant failure rate had the next biggest impact on the ICER, followed by the costs for third or subsequent recurrent heart failure hospitalisations. The committee concluded that heart failure hospitalisations were a key driver of the model.

Heart failure hospitalisation rates

3.16 Heart failure hospitalisation rates were calculated using data from 2 studies done in the UK. 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. Lahoz et al. reported the median number of days to the next heart failure hospitalisation. From this, the EAG calculated the hazard ratio for a recurrent event compared with having no recurrent heart failure hospitalisations after the index heart failure hospitalisation. The EAG used data from COAST to estimate the recurrent heart failure hospitalisation rate in the first stable heart failure state in the Markov model. It did this using data

from Lahoz et al. to adjust for the fact that the COAST data included people with multiple previous heart failure hospitalisations. Data in Lahoz et al. was not reported according to NYHA class. People with NYHA class 3 heart failure were more likely to be admitted to hospital than people with NYHA class 1 or 2. Lahoz et al. data was used to adjust the COAST data to account for the number of previous heart failure hospitalisations. 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.

Utilities

3.17 In the EAG's base case, the utility value for the initial stable heart failure state was based on a published meta-analysis of utilities for people with heart failure (Santos et al. 2024). Reductions in utility were made for the second, third and fourth stable heart failure states using data from Gohler et al. (2009). As people progressed through the subsequent stable heart failure states, their utility declined. The clinical experts agreed that utility declines with each hospital admission. Utility data from the EAG's meta-analysis of trials of the technologies included in this evaluation were not used in the base case. This was because of a high degree of uncertainty in the results.

Alternative scenarios for capturing utilities in the model were considered, in which utility outcome data from the trials was directly applied in the model. In scenario 6a, data was applied from CHAMPION. The EAG had some concerns about using CHAMPION data because of how old it was and because the trial was done in the US. In scenario 6b, data was applied from MONITOR-HF. MONITOR-HF was done in the Netherlands, so was preferred by the EAG because the data was from a European population. But the EAG had concerns about using data from

MONITOR-HF because it took place during the COVID-19 pandemic lockdown. This could have affected the generalisability of the results to usual UK practice. 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 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.

Healthcare professional costs

3.18 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. The technologies can be set with parameters specific to the people using them. Also, they can alert people using them and their healthcare professionals when measurements fall outside of range. The model was based on a band 5 nurse monitoring PAP data. But a band 5 nurse would not be able to prescribe medications if the data shows that a change in medication is needed to avoid decompensation of heart failure. A doctor or nurse prescriber would need to prescribe the medication. Five minutes per month of a medical consultant was included in the base case. This may have been insufficient if a doctor or nurse prescriber is needed to oversee medication changes and prescribe medication. So, the committee thought that the band 5 nurse costs in the model were likely to have been an underestimate.

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. 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.

Primary care resource use was not included in the model because there was no data on it. The clinical experts advised that, in the real world, people using the technology would remain under secondary care. The committee agreed that the omission of primary care resource use was not a limitation.

The cost effectiveness of CardioMEMS

3.19 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. There were also some areas of uncertainty in the model for CardioMEMS, including that:

- monitoring of PAP data was more frequent in the trials than it would be in clinical practice
- reducing the frequency of monitoring in the model may reduce costs.

The committee agreed that there was evidence that CardioMEMS reduced heart failure hospitalisations but that there was uncertainty about the size of the effect. The committee agreed that the clinical effectiveness was likely greater in the trials than in the real-world clinical setting. This was because:

- of the difference in the mean age of the trial population and that of the real-world heart failure population
- there have been changes in the clinical management of heart failure since some of the trials were done

- the intensive monitoring in the trials may have increased the size of the effect.

The committee concluded that, given the cost of CardioMEMS, accounting for these uncertainties in the model would be insufficient to make it cost effective.

The cost effectiveness of Cordella

3.20 The ICER for Cordella could not be estimated because its cost was unknown. In the model, the cost of Cordella was assumed to be the same as the cost of CardioMEMS. This assumption was made to enable Cordella to be included in the model and was for illustrative purposes only. The committee concluded that it was not possible to estimate the cost effectiveness of Cordella.

Preferred model assumptions for this evaluation

3.21 The committee concluded that the base case in this evaluation must:

- 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)
- use the cost of monitoring based on the monitoring schedule that was considered plausible by the committee (see section 3.22).
- 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.

Health Technology Wales model

3.22 The committee was aware that a model was developed for the Health Technology Wales appraisal of percutaneous implantation of PAP sensors for monitoring treatment of chronic heart failure. The ICER in the base case was lower than the ICER in the EAG's

model. The committee discussed the key differences between the models and agreed that it preferred the model developed by the EAG. In the EAG's model, the disutility associated with hospitalisation for heart failure stopped after 1 month, but the disutility lasted for 1 year in the Health Technology Wales model. The committee agreed that 1 month was a more plausible timeframe for disutility because of hospitalisation and immediate recovery. In the EAG's model, the utility associated with each stable heart failure state decreased with each subsequent stable state. The committee agreed that this was clinically appropriate. Also, in the Health Technology Wales model, monitoring costs were based on a band 5 nurse monitoring PAP data. The committee recalled its earlier conclusion that a healthcare professional who can prescribe would need to do the monitoring.

Equality considerations

3.23 The technologies need people to take PAP measurements at home. People with cognitive impairment, problems with manual dexterity or learning disabilities, and people who do not have the necessary digital skills may need additional support to use the technology at home. Support may be provided by healthcare professionals, carers or, if available, digital enablers. The technologies are preprogrammed with a number of languages. If the required language is not preprogrammed, it would need to be added to the technology. Hospital attendance can be a burden, especially for people living in rural or coastal areas, which could involve a long journey on public transport or an expensive taxi. Remote monitoring could help reduce this burden by reducing unplanned and urgent hospital visits.

Technical performance of the technologies is expected to be the same in White ethnic groups and other ethnic groups. But healthcare professionals should be aware of, and account for, other

factors that could affect adherence to using the technologies and medication changes in ethnic minority groups. For example, cultural preferences, beliefs about medical treatment and degree of trust in medical professionals could affect adherence.

4 Committee members and NICE project team

This topic was considered by specialist committee members appointed for this topic and NICE's diagnostics advisory committee, which is a standing advisory committee of NICE.

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

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

Chair

Brain Shine

Chair, diagnostics advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Nancy Pursey

Technical lead

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Technical adviser

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Project manager

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Associate director

ISBN: [to be added at publication]