

MiraQ for assessing graft flow during coronary artery bypass graft surgery

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations	4
2 The technology	5
Description of the technology	5
Current management	6
3 Clinical evidence	7
Summary of clinical evidence	7
Committee considerations.....	9
4 NHS considerations	12
System impact	12
Committee considerations.....	12
5 Cost considerations	13
Cost evidence	13
Committee considerations.....	15
2018 guidance review	15
6 Conclusions.....	17
Appendix A Committee members and NICE lead team.....	18
Medical technologies advisory committee members.....	18
NICE lead team	20
Appendix B Sources of evidence considered by the committee.....	21
Update information.....	23

1 Recommendations

- 1.1 The case for adopting the MiraQ system in the NHS for assessing graft flow during coronary artery bypass graft (CABG) surgery is supported by the evidence. The evidence suggests that intraoperative transit time flow measurement is effective in detecting imperfections that may be corrected by graft revision. This may reduce the incidence of graft occlusion and may reduce perioperative morbidity and mortality.
- 1.2 The MiraQ system is associated with an estimated cost saving of £141 per patient compared with clinical assessment, when it is used routinely for assessing coronary artery bypass grafts during surgery [2018 – see section 5.12].

2 The technology

Description of the technology

- 2.1 The MiraQ cardiac system (MCQ0, MediStim ASA) uses ultrasound for the non-invasive assessment of graft blood flow during coronary artery bypass graft (CABG) surgery. It is intended for use in patients with coronary artery disease who are having CABG surgery. It measures 3 parameters of transit time flow (mean blood flow in ml/minute, pulsatility index and diastolic filling percentage) to assess graft blood flow and check patency.
- 2.2 The MiraQ system measures transit time volume flow using specially designed probes. A microcomputer with a 19-inch touch screen mounted on a moveable trolley is used to control the probes and store their outputs.
- 2.3 The MiraQ system can use 2 types of probes to assess blood flow during CABG procedures (the PS and PQ). These differ in the number of recommended reuses and their method of sterilisation. Only the PS probe is considered in this guidance, because the PQ probe needs ethylene oxide sterilisation, which is not thought to be widely available in the NHS. The probes deliver a bidirectional ultrasound beam across a target vessel and the system analyses the returning signal to calculate the blood flow through the vessel at a default filter setting of 20 Hz. A real-time flow curve is displayed together with the mean blood flow in ml/minute, pulsatility index and diastolic filling percentage. This information can be used to determine whether flow through the graft and its anastomoses is acceptable. If not, then the graft can be explored to detect imperfections and revised as necessary to achieve acceptable blood flow.
- 2.4 The cost of the MiraQ system stated in the sponsor's submission includes £32,000 for the VeriQ 2011 console, and £1,582 for each PS probe. These costs have been updated in the 2017 revision of the cost model to £34,000 for the cardiac MCQ0 console and £1,481 for each probe. [2018]
- 2.5 The claimed benefits of the MiraQ system in the case for adoption presented by the manufacturer are:
- improved outcomes of revascularisation procedures by reducing the risk of early graft failure and adverse events

- reduced hospital stay for some patients by reducing the incidence of complications during and after surgery
- reduced numbers of repeat procedures and treatments for postoperative complications.

Current management

- 2.6 Coronary artery disease is a common cause of symptoms, disability and death. It is caused by atherosclerosis, which leads to stenosis or occlusion of the coronary arteries. NICE clinical guideline 126 on 'Management of stable angina' recommends that revascularisation of the blocked coronary arteries using CABG or percutaneous coronary interventions should be considered in people whose symptoms are not satisfactorily controlled by medical treatment.
- 2.7 CABG aims to bypass narrowed or blocked segments of the coronary arteries using grafts. Grafts are usually constructed from lengths of the patient's own long saphenous vein or their internal mammary artery, although other vessels are also used.
- 2.8 Cardiac surgeons use a variety of techniques to avoid technical imperfections during CABG, but assessment of graft flow is usually subjective. Techniques used vary according to the graft used, the surgical technique, and the surgeon's individual preference. They include the surgeon assessing resistance and perfusion beyond a graft by flushing fluid through it before restoring flow, and both observing and palpating grafts for pulsation when blood flow has been re-established.
- 2.9 There are a number of methods for the objective assessment of the technical results and of blood flow. Transoesophageal echocardiography evaluates heart function after bypass by assessing regional left ventricular wall motion abnormalities, which can be compared with preoperative regional left ventricular function. Perioperative graft flow can be visualised in the operating theatre using conventional angiography or using indocyanine green fluorescence. NICE has produced guidance on 'Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency' (interventional procedures guidance 98). This guidance states that 'current evidence suggests that the procedure is safe enough for routine use in the evaluation of coronary artery bypass graft patency'.

3 Clinical evidence

Summary of clinical evidence

- 3.1 The key clinical outcomes for the MiraQ system presented in the decision problem were:
- incidence of graft failure
 - time to graft failure
 - peri- and postoperative clinical events associated with graft failure (including mortality)
 - frequency of the need for graft revision and changes in VeriQ measurements afterwards
 - the need for repeat coronary revascularisation procedures
 - long-term morbidity and mortality.
- 3.2 The evidence for the clinical effectiveness of the MiraQ system was based on 2 retrospective observational studies that examined surgical outcomes, and one comparative study that compared parameter values from the VeriQ system against another flowmeter. The studies were conducted in hospitals in Europe and Canada; there were none in the UK. All patients in the studies were treated by coronary artery bypass graft (CABG) surgery.
- 3.3 In a retrospective case study in Canada, Kieser et al. (2010) evaluated transit time flow measurement with the VeriQ system to detect technical errors in CABGs intra-operatively and to predict postoperative major adverse cardiac events. They assessed 1,000 arterial grafts in 336 consecutive patients. Three parameters of transit time flow (pulsatility index, flow and diastolic filling percentage) were measured in 990 (99%) of the grafts. A pulsatility index value of less than 5 was chosen as the principal measure of graft adequacy. In 82% of the patients (277 of 336), 93% of grafts (916 of 990) had a pulsatility index of less than or equal to 5. The remaining 74 (7%) grafts (in 59 patients, 18%) had a pulsatility index of greater than 5, but grafts were revised only when an abnormally high pulsatility index was accompanied by other indications of graft malfunction (abnormal electrocardiogram [ECG] changes, regional wall motion

abnormality on transoesophageal echocardiography or haemodynamic compromise). On this basis, 20 grafts (in 14 patients, 4%) that were suspected to be problematic were revised.

- 3.4 For analysis of the findings, patients were divided into 2 groups: the 277 (82%) with at least one graft with a pulsatility index of less than 5, and 59 (18%) with at least one graft with a pulsatility index of greater than 5. Major adverse cardiac events (recurrent angina, perioperative myocardial infarction, postoperative angioplasty, re-operation and/or perioperative death) occurred significantly more often in patients with a pulsatility index of greater than 5 (10 of 59, 17%) when compared with patients with a pulsatility index of less than 5 (15 of 277, 5.4%, $p=0.005$). Mortality following non-emergency surgery was significantly higher in the patient group with a pulsatility index of greater than 5 (5 of 54, 9%) than in the group with a pulsatility index of less than 5 (5 of 250, 2%, $p=0.02$).
- 3.5 Becit et al. (2007) evaluated the effect on the surgical results of CABG of detecting graft dysfunction by intraoperative transit time flow measurement using the VeriQ system in a case-control study in Turkey. A pulsatility index of greater than 5 and diastolic filling percentage of less than 50% were used as the indicators of inadequate flow. The study compared the surgical outcomes for 2 matched series of consecutive patients whose operations were performed by the same surgeons. The study group ($n=100$) had transit time flow measurement during surgery and the control group ($n=100$) did not. Three per cent (9 of 303) of grafts in 9 (9%) patients in the study group were revised on the basis of abnormal transit time measurements, and after revision all flow values and flow patterns improved. No information was presented about graft revision in the control group. The incidence of intra-aortic balloon pump insertion for low cardiac output was significantly lower in the study group compared with the control group (1 of 100 versus 7 of 100, $p<0.05$). Also, perioperative myocardial infarction was significantly lower in the study group compared with the control group (0 of 100 versus 5 of 100, $p<0.05$). There was no statistically significant difference between the patient groups in intraoperative re-exploration for bleeding or deep sternal infection.
- 3.6 Nordgaard et al. (2010) investigated the variation in pulsatility index measurement between 2 different flowmeters (VeriQ and Transonic) and examined whether increasing filtering of the flowmeter signals influenced flow

curves and pulsatility index. The VeriQ and Transonic flowmeters have default filter settings of 20 Hz and 10 Hz respectively. Flow patterns in 19 patients recorded simultaneously by both flowmeters during CABG surgery were analysed. This showed that the VeriQ system provided systematically higher pulsatility index values than the Transonic device (mean \pm standard deviation [SD]: 2.7 ± 1.2 versus 1.8 ± 0.6 respectively, $p < 0.001$).

- 3.7 Clinical evidence was also available from 26 studies on predecessor devices of the VeriQ system which were designed to evaluate the technical performance of devices, to compare them against the other methods of graft flow assessment such as intraoperative fluorescence imaging and postoperative X-ray angiography; and to assess the predictive value of abnormal transit time flow measurement on short and long-term clinical outcomes of CABG surgery. These were evaluated by the external assessment centre and, on balance, their opinion was that the studies showed that transit time flow measurements by the VeriQ system predecessor devices predicted short-term graft failure following CABG surgery and were easier to carry out than other methods. However, they also thought that assessing graft flow with transit time flow measurement alone may prompt unnecessary graft revision in some cases and there is inadequate evidence about whether transit time flow measurement predicts long-term patient survival.

Committee considerations

- 3.8 The committee recognised that graft dysfunction is a major determinant of perioperative morbidity and mortality after CABG. It was advised that the majority of graft failures in the perioperative period are due to technical imperfections which, if recognised, might be corrected at the time of surgery.
- 3.9 The committee noted that perioperative myocardial infarction resulting from graft failure may cause serious complications such as left ventricular dysfunction, ventricular arrhythmias and haemodynamic instability, which can necessitate prolonged intensive therapy unit stay. These complications may need interventions such as intra-aortic balloon pumping, coronary angiography and early reoperative CABG surgery. They may also lead to readmission to hospital.
- 3.10 The committee considered that the available evidence supported the claim that

transit time flow measured by the VeriQ system can identify grafts that have reduced flow as a result of technical imperfections.

- 3.11 The committee recognised limitations in the available evidence. The main studies were observational, with potential for bias. The study by Kieser et al. (2010) investigated the VeriQ system on arterial grafts only, whereas in the NHS the majority of CABGs are vein grafts. Nevertheless, it judged that there was sufficient additional evidence relating to predecessor devices and sufficient expert advice to support the expectation that routinely revising all appropriate grafts on the basis of VeriQ measurements would result in reduced perioperative graft occlusions and consequent complications.
- 3.12 The committee noted from the study by Nordgaard et al. (2010) that pulsatility index values from the VeriQ system may differ from those of other machines and are influenced by filter settings. However, these differences are systematic and expected to be predictable.
- 3.13 The committee was advised that cardiac surgeons use a variety of methods to minimise and detect technical imperfections during CABG surgery but these may have limitations. On the basis of the evidence, it judged that the routine use of VeriQ, as an adjunct to other methods of assessment such as transoesophageal echocardiography, electrocardiography and clinical assessment, would be likely to detect technical problems in some grafts that appear to be satisfactory on clinical assessment alone.
- 3.14 The committee noted that recent joint guidelines on myocardial revascularisation issued by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) have recommended graft evaluation by objective methods before leaving the operating theatre after CABG surgery. These guidelines refer to flow less than 20 ml/minute and a pulsatility index of greater than 5 as predicting technically inadequate grafts that need revision before leaving the operating theatre.
- 3.15 The committee recognised that the clinical outcomes of CABG surgery have improved in the UK in the past 20 years and that complication rates are now very low. However it was advised that there is still a perioperative graft occlusion rate of 1–3%. The committee considered that the VeriQ system has potential to reduce this graft occlusion rate and so further reduce morbidity and

mortality after CABG.

4 NHS considerations

System impact

- 4.1 Approximately 22,500 isolated coronary artery bypass graft (CABG) operations are performed in the UK each year. In addition, a substantial proportion of patients having other cardiac surgery (for example, valve replacement surgery) have concomitant CABG. Based on this large number of patients, any reduction in graft occlusion rates by the MiraQ system during CABG surgery potentially offers significant cost savings to the NHS.
- 4.2 The committee was informed that the MiraQ system is easy to use and does not significantly increase operative time.

Committee considerations

- 4.3 As described in [section 3](#), the committee judged that reduction in graft occlusion rates by MiraQ assessment and appropriate revision at the time of surgery could decrease complication rates. This could reduce the likelihood of subsequent interventions, prolonged intensive therapy unit and hospital stay, and readmission. Each of these reductions would result in significant resource savings.

5 Cost considerations

Cost evidence

- 5.1 The economic evidence for the MiraQ system comprised a new cost analysis to assess the cost savings to the NHS of introducing the MiraQ system for assessing graft flow during coronary artery bypass graft (CABG) surgery, compared against clinical assessment.
- 5.2 In the base-case analysis, the equipment cost for the MiraQ system was about £111 per procedure and the additional time for measuring flow in 3 grafts was 2.35 minutes. The equipment costs were based on the VeriQ 2011 console (purchase cost £32,000 with an anticipated life span of 10 years) and an average use of 1.7 probes per procedure (£1,582 per PS probe, which is recommended for up to 30 uses). The costs per patient were based on the purchase cost of a MiraQ system divided by 220 days' use per year over its life expectancy, including annual maintenance costs. Annual maintenance costs are payable from the end of year 2 at £1,800 per year. It was assumed that the annual maintenance costs for the remaining 8 years would be averaged over the 10-year life expectancy of the equipment. All time costs in the model were based on the salaries of a CABG team comprising 2 cardiothoracic surgeons, 1 anaesthetist, 1 cardiac perfusionist and 2 cardiac nurses.
- 5.3 The cost model evaluated the cost savings of using the MiraQ system compared with clinical assessment alone in assessing graft flow in all patients having CABG. The outcomes considered in the model are complications associated with the CABG surgery.
- 5.4 The consequences of using the MiraQ system were based on results from 2 studies (Kieser et al. [2010] and Becit et al. [2007]). In the base-case analysis, use of the MiraQ system was associated with an increase of 6.6% in the graft revision rate (a 2.3% increase in minor revisions and a 4.3% increase in major revisions). Costs were based on the time taken by the CABG team to perform the revisions. The cost of the time taken to perform a minor revision was estimated to be £11, and for major revisions, £180.
- 5.5 The perioperative events included in the cost analysis were: incidence of postoperative myocardial infarction and the associated rehabilitation costs; use

of intra-aortic balloon pumping; incidence and treatment costs of intraoperative re-exploration for bleeding; and incidence and treatment costs of deep sternal infection. The rates of these events for CABG with and without the MiraQ system were based on Becit et al. (2007). The base-case analysis compared a 0% postoperative myocardial infarction rate for patients assessed clinically and with VeriQ versus a 5% rate for patients who had clinical assessment alone. The treatment costs of postoperative myocardial infarction and associated rehabilitation costs were estimated to be £1,667 per patient. The cost of treatment by intra-aortic balloon pumping was estimated to be £2,657 per episode. The base-case analysis compared a 1% rate for intra-aortic balloon pumping for patients assessed clinically and with VeriQ versus a 7% rate for patients who had clinical assessment alone. There was no difference in the rate of intraoperative re-exploration of bleeding and incidence of deep sternal infection between the arms of the model. No adverse event costs as a result of using the VeriQ system were included in the model because none have been reported.

- 5.6 The cost saving associated with the MiraQ system in the base case was £115 per patient based on purchase of a VeriQ 2011 console (£32,000), using a PS probe (£1,582 for 30 uses), and annual maintenance costs (£1,800) payable at the end of year 2.
- 5.7 The sensitivity analysis based on the parameters and ranges identified by the manufacturer showed that estimates of cost saving for the MiraQ system are robust. The key drivers of the cost saving were the reduction in the rate of postoperative myocardial infarction and the reduction in use of intra-aortic balloon pumping associated with the use of the MiraQ system. The highest cost saving obtained in the sensitivity analysis was £323 per patient and was associated with 0% use of intra-aortic balloon pumping in patients assessed with the MiraQ system compared with a usage rate of 14% in patients assessed without the MiraQ system. The lowest cost saving, of £38 per patient, was obtained for a 2.5% postoperative myocardial infarction rate. The only case in which use of the MiraQ system was not cost saving (when the cost per patient was £45) was when there was no change in the usage rate of intra-aortic balloon pumping in either arm of the model (3.5%). The external assessment centre advised that this is a pessimistic view and that the MiraQ system is likely to be cost saving when used appropriately.

Committee considerations

- 5.8 The committee considered that the assumptions made in the cost model were realistic and that the range of savings calculated for the use of MiraQ was likely to be realised in practice.
- 5.9 The committee noted that the manufacturer's cost model did not include potential cost savings from reductions in intensive therapy unit stay and reduced readmission rates. The cost savings associated with the MiraQ system may therefore have been underestimated.
- 5.10 The committee also noted that the manufacturer's estimated usage of the MiraQ system at 1 patient per day for 220 days per year was likely to be conservative. The committee was advised that on average 3 to 4 CABG operations are performed per day in a cardiac operating theatre in the UK. Increased annual use of a MiraQ system is expected to reduce the estimated equipment cost per procedure because the capital cost of the VeriQ system will be divided across more procedures.
- 5.11 The committee considered that the reductions in perioperative myocardial infarction rate to zero and of intra-aortic balloon pump use from 7% to 1% when using the MiraQ system compared with clinical assessment alone in the base case were likely to be overestimates. This would tend to reduce the estimated cost savings of the MiraQ system. However, the committee noted that sensitivity analysis showed that if using the MiraQ system had no impact on the postoperative myocardial infarction rate or led to only a small change in intra-aortic balloon pumping rates (of less than 2%), the MiraQ system remained cost saving compared with clinical assessment alone, resulting in a saving to the NHS.

2018 guidance review

- 5.12 For the guidance review, the external assessment centre revised the model to reflect 2017 costs (original guidance values are given in brackets). The main parameter changes were the cost of the MiraQ console £34,000 (£32,000) and probes £1,481 (£1,582) with 50 uses (30 uses). These costs resulted in a MiraQ system cost of about £141 (£111) per procedure. The cost of the time taken to perform a minor revision was estimated to be £24 (£11), and for major revisions, £396 (£180). Treatment costs of postoperative myocardial infarction and

associated rehabilitation costs were estimated to be £2031 (£1,667) per patient and treatment cost by intra-aortic balloon pumping was estimated to be £2,574 (£2,657) per episode. Base-case results for the 2017 revised model shows the cost saving associated with the MiraQ system was £141 (£115) per patient. Further details of the 2017 revised model are in the revised model summary [2018].

6 Conclusions

- 6.1 The committee concluded that the available clinical and cost evidence supported the case for adopting the MiraQ system in the NHS for routine intraoperative graft flow assessment in patients having coronary artery bypass graft (CABG) surgery.

Appendix A Committee members and NICE lead team

Medical technologies advisory committee members

The medical technologies advisory committee is a standing advisory committee of NICE. A list of the committee members who took part in the discussions for this guidance appears below.

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 medical technologies advisory committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)

Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)

Consultant Cardiologist, Cardiff and Vale NHS Trust

Dr Dilly Anumba

Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett

Lay member

Professor Bipin Bhakta

Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard

Consultant Radiologist, Leicester Royal Infirmary

Dr Martyn Bracewell

Senior Lecturer in Neurology and Neuroscience, Bangor University

Dr Daniel Clark

Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Karl Claxton

Professor of Economics, University of York

Mrs Gail Coster

Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Craig Dobson

General Practitioner and Senior Lecturer in Medical Education and General Practice, Hull York Medical School

Dr Alex Faulkner

Senior Research Fellow, Centre for Biomedicine & Society, King's College London

Professor Tony Freemont

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Mr Harry Golby

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Mr Matthew Hill

Lay member

Dr Paul Knox

Reader in Vision Science, University of Liverpool

Ms Catherine Leonard

Reimbursement Manager, Medtronic UK

Dr Susanne Ludgate

Clinical Director, Devices Medicines and Healthcare Products Regulatory Agency

Professor Christopher McCabe

Professor of Health Economics, Institute of Health Sciences, University of Leeds

Mrs Jacqui Nettleton

Programme Director, Long Term Conditions, West Sussex PCT

Professor Sharon Peacock

Professor of Clinical Microbiology, University of Cambridge

Dr Allan Swift

Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

Professor Stephen Westaby

Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Janelle York

Lecturer and Researcher in Nursing, University of Salford

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory committee and a representative of the external assessment centre.

Mukesh Dhariwal

Technical Analyst

Lizzy Latimer

Technical Adviser

Ian Wilson

Lead Expert Adviser

Harry Golby

Non-Expert MTAC Member

Chris Lawinski and Donald Emerton

External Assessment Centre Representatives

Appendix B Sources of evidence considered by the committee

1. The external assessment centre report for this assessment was prepared by KCARE:
 - Lawinski C, Emerton D and Kazantzi M, KCARE. VeriQ system for assessment of graft flow during coronary artery bypass graft (May 2011).
2. Submissions from the following sponsor:
 - Medistim ASA.
3. The following individuals gave their expert personal view on the VeriQ system by providing their expert comments on the draft scope and assessment report.
 - Mr Simon Kendall, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
 - Mr Peter O'Keefe, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
 - Mr Ian Wilson, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
4. The following individuals gave their expert personal view on the VeriQ system in writing by completing a patient questionnaire or expert adviser questionnaire provided to the committee.
 - Professor Gianni Angelini, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
 - Mr Simon Kendall, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
 - Mr Stephen Large, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
 - Mr Peter O'Keefe, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.
 - Mr Andre Simon, German Society of Thoracic and Cardiovascular Surgeons – clinical expert.
 - Mr Ian Wilson, Society for Cardiothoracic Surgery, Great Britain and Ireland – clinical expert.

- expert.

Update information

February 2018: Having originally been developed to make recommendations on the use of VeriQ, this guidance has been updated to make recommendations on the use of a follow-on technology, MeriQ. The recommendations, committee considerations and evidence for VeriQ apply to the new technology. The technology name has been changed where relevant from VeriQ to MiraQ. New evidence and updated costs identified during the guidance review are denoted as [2018].

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Accreditation

