NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

DyeVert Systems for reducing contrast media in coronary and peripheral angiography

1 Technology

1.1 Description of the technology

DyeVert Contrast Reduction System (DyeVert Systems; Osprey Medical Inc) is a non-invasive system designed to reduce the amount of contrast media given during coronary and peripheral angiography, within a cardiac catheterisation or vascular radiology suite. There are 2 DyeVert Systems models. DyeVert Plus EZ Contrast Reduction System is compatible with manual contrast injection systems. DyeVert Power XT Contrast Reduction System is compatible with power or automated contrast injection systems.

DyeVert Systems reduces contrast given using a modifiable valve which responds to injection pressure and fluid pathway resistance. This reduces the total contrast media volume delivered during coronary or peripheral imaging, whilst maintaining adequate image quality.

It is designed for people at risk of acute kidney injury (AKI), including those with moderate to severe chronic kidney disease, diabetes, and heart failure. By reducing the amount of contrast volume given, DyeVert Systems aims to reduce the risk of contrast induced-AKI (CI-AKI).

The DyeVert PLUS EZ System consists of:

- A disposable module, which attaches to an injection port, has a standard valve which allows for opening and closing the system to the manifold, a

reservoir for storing excess dye and a contrast collection bag for disposing of diverted contrast at the end of the procedure.

- A disposable smart syringe which connects to the manifold to deliver dye injections.

- A reusable monitor which shows real-time dye delivery amounts including volume per injection, cumulative volume delivered and volume remaining until threshold dose is reached. The monitor also allows predefined maximum contrast media thresholds to be entered and provides a historical contrast use summary.

The DyeVert PLUS EZ disposable module is positioned between the manual syringe (smart syringe) and the injection port (manifold). The clinician controls the injection of contrast manually using the smart syringe. Excess contrast not needed for diagnostic or therapeutic purposes is removed. The clinician is still in control of the amount of dye given and the redirection valves can be closed to give more contrast. The monitor display can help inform the clinician's decisions about how much dye to give.

The DyeVert Power XT Contrast Reduction System consists of a disposable module and smart bag. The disposable module, which has a diversion line and 2 catheter size-dependent diversion valves, attaches to the automated injector connection and the angiographic catheter used to deliver contrast media into the vascular system. The smart bag collects and digitally displays diverted contrast media volume in real-time throughout the procedure.

1.2 Relevant diseases and conditions

DyeVert Systems is intended for use in people at risk of CI-AKI as a result of cardiovascular or peripheral angiography.

NICE's evidence review on acute kidney injury: prevention, detection and management states that CI-AKI is uncommon in the general population, with an incidence of 1 to 2%. CI-AKI occurs within 72 hours of receiving iodinated contrast media, with the individual usually recovering over the following 5

days. Its incidence increases significantly in people with certain risk factors and is associated with prolonged hospital stay, increased mortality and increased health care costs. The risk of CI-AKI has been reported to be as high as 25% in certain people in at risk groups such as those with chronic kidney disease (CKD) and diabetes.

Ozkok et al (2017) reported that the incidence of CI-AKI is higher in people who already have CKD, in those who are critically ill and in people who have contrast enhanced imaging performed as an emergency. Short and long-term mortality rates have been found to be significantly higher in people with CI-AKI compared with those without CI-AKI. A history of CI-AKI may be associated with the development of CKD and progression to end stage renal disease. Prasad et al (2020) found that CI-AKI led to an increased risk of in-hospital mortality and hospital readmission. This incidence was higher in people with CKD. Gurm et al (2016) suggests that a 30% reduction in contrast dye use could prevent 1 in 8 cases of CI-AKI.

1.3 Current management

NICE's guideline on acute kidney injury: prevention, detection and management states that increasing volume of contrast agent given is a risk factor for AKI. This means that people who are going to have contrast agents should be assessed for their risk of AKI for non-emergency imaging and that the risks of developing AKI are part of the routine discussion of risks and benefits of the imaging procedure. CKD should be investigated by measuring estimated glomerular filtration rate (eGFR) or by checking an eGFR result obtained within the past 3 months. Emergency imaging should not be delayed but clinicians should be aware of those who are at increased risk of developing CI-AKI including those with:

- CKD (adults with an eGFR less than 40 ml/min/1.73 m^2 are at particular risk)
- diabetes with CKD
- heart failure

- renal transplant
- aged 75 years or over
- hypovolaemia
- increasing volume of contrast agent
- intra-arterial administration of contrast medium with first-pass renal exposure.

NICE's diagnostic guideline on point-of-care creatinine devices to assess kidney function before CT imaging with intravenous contrast states that the threshold for eGFR at which there is a risk of developing CI-AKI varies across different guidelines. These thresholds range between an eGFR less than 30 ml/min/1.73 m^2 (The Royal Australian and New Zealand College of Radiologists iodinated contrast guidelines, which have been endorsed by the Royal College of Radiologists) and an eGFR less than 60 ml/min/1.73 m^2 (Prevention of Contrast Induced Acute Kidney Injury (CI-AKI) In Adult Patients). Clinical experts suggested that people with an eGFR of less than 30 ml/min/1.73 m^2 are at highest risk of developing CI-AKI.

NICE's guideline on acute kidney injury: prevention, detection and management encourages oral hydration before and after procedures that use intravenous iodine-based contrast media in adults at increased risk of contrast-induced acute kidney injury. It also recommends considering intravenous volume expansion with either isotonic sodium bicarbonate or 0.9% sodium chloride if they are at particularly high risk. People at high risk include those that have:

- an eGFR less than 30 ml/min/1.73 m^2
- had a renal transplant
- received a large volume of contrast medium (for example, higher than the standard diagnostic dose or repeat administration within 24 hours)

- intra-arterial administration of contrast medium with first-pass renal exposure.

This guideline also suggests temporarily stopping angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers in adults having iodine-based contrast media if they have chronic kidney disease with an eGFR less than 40 ml/min/1.73 m^2. It is recommended that the person's care be discussed with a nephrology team before offering iodine-based contrast media to adults on renal replacement therapy, including people with a renal transplant, but not to delay emergency imaging for this.

The Kidney Disease, Improving Global Outcomes (KDIGO) clinical practice guideline for AKI recommends using either iso-osmolar or low-osmolar iodinated contrast media (rather than high-osmolar) in people at increased risk of CI-AKI. The European Society of Urogenital Radiology guidelines on contrast media recommends that the lowest dose of contrast medium consistent with a diagnostic result be used and that low or iso-osmolar contrast media be selected. For at-risk people, the guidelines also recommend considering an alternative imaging method without iodinated contrast media as well as preventative hydration.

1.4 Regulatory status

The DyeVert PLUS EZ Contrast Reduction System and DyeVert Power XT Contrast Reduction System first received their CE mark in August 2014 as a class I device for control, reduction and modulation of injection of contrast media into the peripheral and cardiovascular system.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Reduction in CI-AKI incidence
- Contrast agent volume monitoring
- Maintaining good image quality

- Total contrast media volume reduction (on average 40%) because of diversion of contrast agent on each injection
- Contrast agent reflux reduction
- More likely to get contrast administration at or below the maximum contrast media dose
- Reduction in CI-AKI associated morbidity, in-hospital mortality and post-procedure readmissions.

The benefits to the healthcare system claimed by the company are:

- Real-time contrast media dose monitoring relative to the maximum dose target and recording
- Reduced number of bed stays or length of stay in hospital post percutaneous coronary intervention and angiography
- Reduced costs for treating CI-AKI
- Reduced associated treatment costs including drugs or readmissions due to lower long-term adverse events worsening chronic kidney disease, developing major adverse kidney events, end stage renal disease, and major cardiovascular events
- Reduced clinical staff time.
- Improved adherence to recommended guidelines for contrast minimisation as part of an initiative to reduce CI-AKI
- Improved access of coronary and peripheral angiography to people with CI-AKI risk factors.

2 Decision problem

Population	People at risk of contrast-induced acute kidney injury (CI-AKI) who need coronary or peripheral angiography with contrast media.
Intervention	DyeVert Systems used as an adjunct to standard NHS clinical practice.
Comparator(s)	Conventional hand or automated injection of contrast agent.
Outcomes	The outcome measures to consider include: • CI-AKI incidence • CI-AKI severity

	• Measures of renal function, such as serum creatinine concentration, estimated glomerular filtration rate and urine output • Volume of contrast agent received and diverted • Image quality • Length of hospital stay and rates of re-admission as a result of CI-AKI or acute heart failure (suspected cause by contrast agent) • Rate of acute heart failure with suspected cause by contrast agent • Rate of renal replacement therapy, intensive care transfer or mortality as a result of CI-AKI • Device-related adverse events.	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which can include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	Identifiable subgroups who may be at particularly high risk of developing CI-AKI.	
Special considerations, including those related to equality	People with chronic kidney disease, heart failure, diabetes, and renal transplant would be more at risk of CI-AKI. Kidney disease occurs more frequently in males, people over the age of 60, and those of African-Caribbean, African or South-Asian family origin. People who have an ileostomy and older people are at an increased risk of becoming dehydrated and may need special consideration. Conditions including alcoholism and hypoalbuminemia may also affect the ability to have pre- and post-scan hydration.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Tests to help assess risk of acute kidney injury for people being considered for critical care admission (ARCHITECT and Alinity i Urine NGAL assays, BioPorto NGAL test and NephroCheck test) (2020) NICE diagnostics guidance DG39
- COVID-19 rapid guideline: acute kidney injury in hospital (2020) NICE guideline NG175
- Point-of-care creatinine devices to assess kidney function before CT imaging with intravenous contrast (2019) NICE diagnostics guidance DG37
- Acute kidney injury: prevention, detection and management (2019) NICE guideline NG148
- Acute kidney injury (2014) NICE quality standard QS76

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association for Nursing Cardiovascular Care
- British Cardiovascular Intervention Society
- British Heart Foundation
- British Institute of Radiology
- British Renal Society
- British Society for Heart Failure
- British Society of Cardiac Radiology
- British Society of Cardiovascular Imaging
- British Society of Interventional Radiologists
- National Kidney Federation
- Renal Association
- Royal College of Radiologists
- Society for Cardiological Science and Technology

- Society for Vascular Technology
- The Society for Cardiothoracic Surgery
- The Vascular Society of Great Britain and Ireland.

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- British Cardiac Patients Association (BCPA)
- British Heart Foundation (BHF)
- Diabetes UK
- Kidney Care UK
- Kidney Research UK
- Pumping Marvellous