NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Curos disinfecting cap for infection prevention in needleless connectors

1 Technology

The Curos disinfecting cap (3M) is a single-use device used to protect needleless connectors of vascular access devices. Curos contains foam impregnated with 70% isopropyl alcohol, which is capable of killing micro-organisms commonly responsible for central-line-associated bloodstream infections (CLABSI). The caps are packaged individually or in strips of 10 caps which can be hung from an IV pole. The caps are twisted onto the end of needleless connector points (ports). It is claimed that within 1 minute of application, the cap will have killed 6 common micro-organisms associated with CLABSI, after which it can be removed to give immediate access to the needleless connector. Alternatively, the cap can remain in place to provide a physical barrier to contamination for up to 7 days. Curos cannot be reused once removed.

1.1 Description of the technology

1.2 Regulatory status

The Curos received a class IIa CE mark in September 2016.

1.3 Claimed benefits

The benefits to patients claimed by the company with the use of Curos are:

- Disinfects needleless connectors within 1 minute and for up to 7 days protecting against contamination leading to decreased CLABSI rates.
- Reduced mortality as a result of reduced risk of CLABSI.

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

- More consistent application of IV access disinfection protocols leading to a reduction in the rate of CLABSI.
- Reduced length of stay and reduced intensive care bed days for treatment of CLABSI.
- Cost savings due to reduced time required for healthcare professionals to perform IV access disinfection protocols.

1.4 Relevant diseases and conditions

Curos would be used as part of a bundle of infection prevention measures used to reduce the risk of CLABSI. The Curos disinfecting cap is intended for use on needless connectors of IV access devices (such as peripherally inserted central catheters and tunnelled and non-tunnelled central venous catheters) which may be required in the management of a wide range of conditions and can be used in any care setting. IV access devices are inserted to allow the administration of drugs directly into the bloodstream and may be required to remain in place for many days. During this time treatments are frequently administered through the line, each time this happens there is a risk of introducing microorganisms that can cause CLABSI. CLABSI causes fever and red skin and soreness around the access site and is associated with the need for additional treatment that may include line changes and prolonged antibiotic treatment. The consequences of CLABSI increased morbidity and mortality, length of stay and healthcare costs.

1.5 Current management

According to NICE clinical guidelines and public health guidelines (see section 3) needleless connectors should be disinfected for at least 15 seconds using alcohol wipes or an alcohol containing solution of chlorhexidine gluconate, before and after use. This method requires the disinfected needleless connector to dry before it can be used which takes at least 15 seconds. If Curos is used, a new Curos cap is placed over the connector each time it is used. This means that healthcare staff do not have to spend time disinfecting

the connector and waiting for it to dry every time the needleless connector is used.

2 Statement of the decision problem

	Draft scope issued by NICE	
Population	People with vascular access devices in hospital and community settings	
Intervention	Curos disinfecting cap	
Comparator(s)	• alcohol wipes • alcohol containing solution of chlorhexidine gluconate	
Outcomes	The outcome measures to consider include: • time taken to complete disinfect • overall staff time • infection rates (CLABSI and catheter-related bloodstream infections) • mortality • length of hospital stay • length of time vascular access device in place • device-related adverse events • improved consistency in disinfection protocols • reduced use of chlorhexidine • environmental impact of reduced number of wipes disposed and increased plastic waste	
Cost analysis	Comparator(s): Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	People who are at high risk of infection	
Special considerations, including those related to equality	Curos may be used with vascular access devices in people with chronic diseases who are considered disabled under the equality act. This will include people with cancer and may include people with chronic kidney disease, cystic fibrosis, sickle cell disease, thrombotic thrombocytopenic purpura, Sjogrens syndrome, Guillian-Barre syndrome, myasthenia gravis and lysosomal storage disorders.	
Special considerations, specifically related to equality issues	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 characteristics?	Yes
	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 MTAC will have relevant information to consider equality issues when developing guidance?	No
	Curos might present a choking risk for children and people with cognitive difficulties if left within reach.	

3 Related NICE guidance

Published

- Healthcare-associated infections: prevention and control in primary and community care (2012) NICE Clinical guideline CG139
- Healthcare-associated infections: prevention and control (2011) NICE Public health guideline PH36
- Curos disinfecting cap for needleless connectors (2018) NICE Medtech innovation briefing MIB143

Guidance from other organisations

- Epic 3 guidelines for preventing healthcare associated infections (2017) NHS Improvement

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations contacted for expert advice and invited to comment on the draft scope

The following societies were contacted to provide nominations of expert advisers and have been alerted to the availability of the draft scope for comment:

- Association of Surgeons in Primary Care
- British Cardiovascular Intervention Society
- British Cardiovascular Society
- Intensive Care Society
- The Royal College of Anaesthetists
- Royal College of Nursing
- Royal College of Physicians
- British Association of Critical Care Nurses
- National Infusion and Vascular Access Society
- Healthcare infection society

- British Infection Association
- British Association for Community Child Health
- NHS Blood and Transplant
- Paediatric Intensive Care Society
- Royal College of Emergency Medicine
- Royal Institute of Public Health and Hygiene
- Society of Vascular Nurses
- The Vascular Society