NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

ClearGuard HD Antimicrobial Barrier Cap for preventing haemodialysis catheter-related bloodstream infections.

1 Technology

1.1 Description of the technology

ClearGuard HD Antimicrobial Barrier Cap (ICU Medical) is for use with central venous catheters (CVC) in haemodialysis. The cap includes a rod that extends into the CVC hub. Both the rod and cap threads are coated with chlorhexidine acetate, a broad-spectrum antimicrobial agent. Chlorhexidine acetate is intended to reduce the presence of pathogenic organisms in the CVC lock to reduce the risk of catheter-related bloodstream infections (CRBSI). When the ClearGuard HD cap is inserted into the liquid-filled catheter, chlorhexidine acetate is released from the rod into the catheter lock solution. The antimicrobial agent is held inside the catheter hub in between treatments using the existing catheter clamp. ClearGuard HD caps are used in place of a standard cap or connector and need to be replaced during every dialysis session, it cannot be reused once removed. The recommended maximum use time for the cap is 3 days. The ClearGuard HD cap is intended to replace the need to clean the connector port with 2% chlorhexidine in 70% alcohol and then have to wait for it to air dry.

1.2 Relevant diseases and conditions

The ClearGuard HD antimicrobial cap is intended for use on central venous catheters to reduce the risk of catheter related bloodstream infections

(CRBSI) in the management of haemodialysis for end stage kidney disease (ESKD).

End stage kidney disease is an irreversible and progressive deterioration in kidney function. Haemodialysis is a type of renal replacement therapy (RRT) used for ESKD. According to the 22nd annual report by the UK Renal Registry (on 31st December 2018), 36.8% (24,366 adults) of the adult UK RRT (dialysis and transplant) population received haemodialysis in hospital or specialist renal units for ESKD. And a further 11.4% (107) children and young people receiving haemodialysis as their treatment option for ESKD.

Haemodialysis requires intravenous (IV) access to allow blood to flow outside of the body to be filtered through a dialysis machine, it also enables the administration of drugs and fluids directly into the blood. This may be required to remain in place for days to months. Types of haemodialysis access most commonly involve central venous catheters and arteriovenous fistula. A non-cuffed central venous catheter is used for emergency, acute and shorter-term dialysis. More routinely tunnelled (cuffed) central venous catheters are utilised for dialysis. These catheters are placed under the skin and include a cuff to inhibit the migration of microorganisms and attempt to minimise CRBSI. Arteriovenous fistula (AVF) is used for a longer-term dialysis access point, which is a surgically created access point made between an artery and vein. Each time treatments are administered through an access point there is a risk of introducing microorganisms that can cause blood stream infections. It is considered that the rate of bloodstream infections (BSIs) is higher in more temporary access approaches.

CRBSI causes fever, red skin and soreness around the access site and is associated with the need for additional treatment that may include line changes, prolonged antibiotic treatment, prolonged hospital stays, increased risk of morbidity, mortality and resultant healthcare costs.

1.3 Current management

NICE Guideline for renal replacement therapy promotes the choice of dialysis mode and location be discussed with the individual and family encompassing clinical considerations and individual preference. The UK Renal register (31/12/2018) reported the majority of haemodialysis to take place in hospital or community clinic setting with only 4% of the haemodialysis being carried out in the home setting. The coronavirus pandemic has highlighted the benefits of home dialysis and although statistics are not yet available, it may well impact on the uptake of home dialysis seen in the future. Haemodialysis in clinic routinely takes place three times a week, for 3-5 hours, but duration and frequency can vary in the home setting.

When managing haemodialysis using central venous catheters (CVC) NICE clinical guideline for healthcare-associated infections: prevention and control in primary and community care recommends decontaminating the vascular access device catheter hub before and after accessing the system. This consists of scrubbing the connector hub of the CVC before and after each access to the catheter with 2% chlorhexidine gluconate in 70% alcohol wipes and allow the hub to air dry, for a minimum of 15 seconds (NICE, 2017). This method requires the CVC cap to dry before it can be used which takes at least 15 seconds.

1.4 Regulatory status

ClearGuard HD Antimicrobial Barrier Cap received a CE mark in April 2019 as a class IIb device for haemodialysis catheters.

1.5 Claimed benefits

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

- Reduced risk of catheter related bloodstream infections (CRBSI)
- Reduced hospital attendances and length of stay due to CRBSI
- Reduced mortality as a result of reduced risk of CRBSI

Improved patient experience through the prevention of avoidable infections and reduced length of inpatient stay.

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

- Reduced length of stay and reduced intensive care bed days for treatment of CRBSI
- Reduced readmissions due to CRBSI
- Cost savings due to reduced need for antibiotic use, replacement of CVC and critical care cost for treatment of CRBSI
- Reduced mortality as a result of reduced risk of CRBSI.

2 Decision problem

Population	People with central venous catheters undergoing haemodialysis
Intervention	ClearGuard HD antimicrobial cap in place of standard care

Comparator(s)	• Standard CVC caps, decontaminated using;
	  ○ Alcohol wipes
	  ○ Alcohol containing solution of chlorhexidine gluconate
	  ○ Clorox wipes
	  ○ Line lock solutions
	• Alternative disinfecting caps, with / without needleless connectors.

Outcomes	The outcome measures to consider include: • incidence of infection, this might be in the form of; catheter related bloodstream infection (CRBSI), catheter related infection (CRI), central line associated bloodstream infection (CLABSI), positive blood cultures (PBC), access related bloodstream infections (ARBSI) • hospital admissions for bloodstream infection (BSI) • length of stay • mortality • reinsertion of CVC lines • intravenous antibiotic use • time taken to disinfect • overall staff time • environmental impact of number of wipes disposed and number of caps disposed of • reduced use of chlorhexidine • 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 will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	○ Settings for haemodialysis using central venous catheters include community and hospital settings.	
Special considerations, including those related to equality	ClearGuard HD may be used with central venous catheters for haemodialysis for end stage kidney disease (Stages 4 and 5). People who have dialysis which impairs their day-to-day functioning are protected as a disability under the equality act. Kidney disease occurs more frequently in males, people over the age of 60 and those of South-Asian, African or African-Caribbean family origin.	
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
	This device is indicated for use for haemodialysis. Some people with chronic kidney disease have haemodialysis. People with chronic kidney disease are covered by the Equality Act 2010, but this device does not pose an equality issue as access to the device is not restricted.	
Any other special considerations	• Antimicrobial stewardship considerations • People with known allergy to chlorohexidine • People with allergies to nylon or polypropylene	

3 Related NICE guidance

Published

- ClearGuard HD Antimicrobial Barrier Cap for preventing haemodialysis catheter related bloodstream infections (2020) Medical technology innovation briefing [MIB234]

- Renal replacement therapy options in critical care (2020) NICE COVID-19 NHSE/ I specialty guide
- Curos for preventing infections when using needleless connectors (2019) NICE guidance [MTG44].
- Renal replacement therapy and conservative management (2017) NICE guideline [NG107]
- Healthcare-associated infections: prevention and control in primary and community care (2017) NICE guideline CG139
- Healthcare-associated infections (2016) NICE Quality standard [QS113]
- Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use (2015) NICE Guideline [NG15]
- Infection prevention and control (2014) NICE Quality standard [QS61]
- Chronic kidney disease in adults: assessment and management (2014) Clinical Guideline [CG182]
- Guidance on the use of ultrasound locating devices for placing central venous catheters (2002) Technology appraisal guidance [TA49]

In development

NICE is developing the following guidance:

- Chronic kidney disease: assessment and management (update). In development [GID-NG10118]. Expected publication date 20 July 2021.

4 External organisations

4.1 Professional

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

- Association of Nephrology Nurses
- British Association of Critical Care Nurses
- British Association of Paediatric Nephrology
- British Association of Parenteral and Enteral Nutrition
- British Infection Association
- British Renal Society

- European Kidney Health Alliance
- Healthcare Infection Society
- Infection Prevention Society
- Intensive Care Society
- International Society of Nephrology
- National infusion and Vascular access society
- NHS Blood and Transplant
- Paediatric Intensive Care Society
- Renal Physicians Association
- Royal College of Nursing
- Royal College of Physicians
- Royal Society of Medicine
- Society for General Microbiology
- The UK Renal Register
- The Renal Association.

4.2 Patient

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

- Kidney Care UK
- Kids Kidney Research.
- Kidney Research UK
- National Kidney Federation