NICE advice

# Tegaderm CHG securement dressing for vascular access sites

Medtech innovation briefing
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## Summary

- The **technology** described in this briefing is Tegaderm CHG IV securement dressing. It is used to secure vascular access devices and contains an integrated chlorhexidine gluconate (CHG) gel pad. This pad is designed to reduce catheter-related bloodstream infections.
- The **innovative aspects** are that it is the only securement dressing available containing CHG. The dressing is transparent so that the access site can be continually monitored.
- The intended **place in therapy** would be to secure vascular access devices for haemodialysis in people with tunnelled central venous catheters, intravenous (IV) chemotherapy in people with cancer, people who need total parenteral nutrition and children's intensive care. NICE has published guidance on using Tegaderm CHG IV securement dressings in critically ill adults who need a central venous or arterial catheter in intensive care or high dependency units.

- The **main points from the evidence** summarised in this briefing are from 6 studies, including 3 randomised controlled trials, with a total of 1,273 people, including children needing vascular access in intensive care and adults needing vascular access for chemotherapy, dialysis, or total parental nutrition. They show that Tegaderm CHG is more effective at reducing catheter-related infections than standard sterilised dressings in people needing dialysis or chemotherapy.
- **Key uncertainties** around the evidence or technology are that the evidence for reducing catheter-related infections in children's intensive care and adult total parenteral nutrition are from small studies.
- The **cost** of Tegaderm CHG is £4 to £5.04 per unit (excluding VAT).

# The technology

Tegaderm CHG IV securement dressing (3M) is a sterile, semi-permeable polyurethane adhesive dressing with an integrated gel pad containing 2% w/w chlorhexidine gluconate (CHG). It is used to secure percutaneous devices and to cover and protect central venous and arterial catheter insertion sites. The aim is to form a barrier against external contamination. The integrated CHG gel pad is designed to reduce skin and catheter colonisation by microorganisms commonly linked to catheter-related bloodstream infections (CRBSI) at the catheter insertion site.

Catheters are placed with a large securement tape strip. This helps to make sure they're consistently and correctly applied, as well as improving catheter securement. The securement strip is perforated so that it can be opened to help remove the dressing. The body of the dressing also has a perforated keyhole notch so that it can conform around different catheter types and sizes.

NICE published guidance on Tegaderm CHG for central venous and arterial catheter insertion sites in July 2015. When it was reviewed in 2019, evidence in patient populations outside the scope of the original guidance was identified. This briefing summarises evidence for Tegaderm CHG in those populations: people needing vascular access devices in dialysis, chemotherapy, total parenteral nutrition, and children's intensive care.

## Innovations

Tegaderm CHG is the only securement dressing available containing CHG. The dressing is

transparent to allow continual monitoring of the access site.

# Current care pathway

Current standard care is to decontaminate the skin at a vascular access device insertion site with CHG in 70% alcohol. This is then allowed to air dry before inserting the device. The insertion site is covered with a sterile, transparent semi-permeable membrane dressing. This is changed every 7 days, or sooner if it is no longer intact or if moisture collects under it. A sterile gauze dressing, covered with a sterile transparent semi-permeable dressing, should be considered only if the patient has profuse perspiration, or if the vascular access device insertion site is bleeding or oozing. Healthcare workers should also make sure that catheter site care is compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on healthcare-associated infections: prevention and control in primary and community care
- NICE's quality standard on infection prevention and control
- epic3: national evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England.

# Population, setting and intended user

Tegaderm CHG is primarily used for patients who need a vascular access device, to reduce the risk of catheter colonisation, CRBSIs and exit site infections. This includes people having dialysis, people on chemotherapy, people needing total parenteral nutrition, and children in intensive care.

For people on haemodialysis via a central venous catheter, Tegaderm CHG is used at the catheter exit site. The company said that 25.7% of people needing haemodialysis start treatment using a non-tunnelled (temporary) line. These include people with acute kidney injury who need short-term dialysis and people with chronic kidney disease who may have a non-tunnelled line for the first few months of treatment. Tegaderm CHG may benefit this population because they are at higher risk of developing a CRBSI.

For people on chemotherapy, Tegaderm CHG is indicated for people who need longer-term intravenous (IV) chemotherapy, during which a venous access device remains in place until the course of treatment is completed, usually at least 12 weeks.

Total parental nutrition may be given to people having chemotherapy, or in other instances when additional nutritional support may be required. Nutrition is delivered via a non-tunnelled central venous catheter.

For children in intensive care, Tegaderm CHG can be used to secure central venous catheter or peripherally inserted central catheter (PICC) lines. It should not be used in babies under 2 months old because it may cause hypersensitivity reactions or necrosis of the skin. The company said that the safety and effectiveness of Tegaderm CHG dressings have not been evaluated in children under 18.

Tegaderm CHG is intended for use by people who normally apply and change dressings at vascular device insertion sites. These are typically vascular access specialist nurses, mostly in primary care, outpatient dialysis or chemotherapy clinic.

# Costs

## Technology costs

The dressing is available in 4 sizes: 1660R (7 cm × 8.5 cm), 1658R (10 cm × 12 cm), 1659R (10 cm × 15.5 cm) and 1657R (8.5 cm × 11.5 cm).

Different sizes are used for different purposes, and usually as follows for:

- Haemodialysis: 1657R and 1658R
- Chemotherapy: 1657R or 1658R for internal jugular, subclavian, femoral, or tunnelled central venous catheters; 1659R for PICC and mid-line applications
- paediatric central venous catheters and PICC lines: 1657R and 1660R for smaller children
- total parenteral nutrition: 1657R or 1658R for internal jugular or subclavian non-tunnelled central venous catheters; 1659R for a PICC line.

The company said Tegaderm CHG costs between £4 and £5.04 per dressing, excluding

VAT. Each dressing needs to be changed at least every 7 days.

### Costs of standard care

A standard catheter dressing (defined as a vapour-permeable adhesive film sterile IV dressing) costs from £0.83 to £5.70 depending on size, brand, and use. Each dressing needs to be changed at least every 7 days.

A comparator product, Biopatch (see NICE's briefing on Biopatch for venous or arterial catheter sites), costs £4.44 per patch. This is a hydrophilic foam dressing impregnated with CHG, which is applied under a standard sterile transparent semi-permeable IV dressing.

## Resource consequences

Tegaderm CHG is widely used in adult intensive care in the NHS. It is also used for vascular access in adults in haemodialysis and chemotherapy, and in children's intensive care and oncology units. If Tegaderm CHG was more widely used outside adult intensive care, it could reduce catheter-related infections in other populations needing longer-term vascular access. This could reduce the cost of treating infections, and the need for antibiotic use. It could also reduce the need to change catheters, and could improve patient outcomes.

No additional resources are needed to use this technology and the company provides free training. This includes:

- training on the correct use and application of Tegaderm CHG onsite and remotely
- trust-specific training resources and materials, video and web-based resources
- e-resources including 3M Health Care Academy
- webinars and on-demand learning modules
- IV forums and summits

- patient information leaflets.

  Healthcare professionals may also need awareness training about chlorhexidine allergy according to chapter 17 of National Audit Projects (NAP) 6: perioperative anaphylaxis.

# Regulatory information

Tegaderm CHG IV securement dressing is a CE-marked class III medical device.

# Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Tegaderm CHG IV securement dressing would benefit people needing chemotherapy and people on dialysis. Cancer and needing dialysis are classified as disabilities. Tegaderm CHG should not be used in babies under 2 months old. Age and disability are protected characteristics under the Equality Act 2010.

# Clinical and technical evidence

A literature search was carried out for this briefing in accordance with NICE's interim process and methods statement for the production of medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

## Published evidence

Six studies are summarised in this briefing. This includes 3 randomised controlled trials, 1 crossover study, 1 prospective audit and 1 prospective comparative study. A total of 1,273 people were included in the studies.

The clinical evidence and its strengths and limitations is summarised in the overall

assessment of the evidence.

# Overall assessment of the evidence

The evidence covers different populations, outside adult intensive care, who need securement of a vascular access device. Evidence showed that using Tegaderm CHG IV securement dressing during dialysis and chemotherapy reduced catheter-related infections. However, there was less evidence of a benefit in paediatric intensive care and parenteral nutrition. This could be because the studies were smaller, and because of the low level of bloodstream infections in the control groups. Larger randomised controlled trials are needed in paediatric intensive care and parenteral nutrition. Only 1 study was done in the UK, which may limit generalisability to the NHS.

## Biehl et al. (2016)

### Study size, design and location

A multicentre, randomised controlled trial of 613 people having chemotherapy with expected chemotherapy-induced neutropenia in Germany.

### Intervention and comparator

Intervention: Tegaderm CHG dressing.

Comparator: Standard sterilised dressing.

### Key outcomes

Overall incidence of definite and probable catheter-related bloodstream infections (CRBSI) was significantly lower in the Tegaderm CHG group than the control group (10.4% compared with 17.3%; p=0.014). Definite and probable CRBSI infection within 14 days of central venous catheter placement was also significantly lower in the Tegaderm CHG group than the control group (6.5% compared with 11.1%; p=0.047). However, the definite CRBSI rate within 14 days of central venous catheter placement was not significantly different (2.6% for the Tegaderm CHG group and 3.9% for the control group; p=0.375).

### Strengths and limitations

This trial has similar demographics, Eastern Cooperative Oncology Group (ECOG) score, duration of neutropenia, and central venous catheter insertion site and type between groups. This study was funded by the company and was not done in the UK.

## Apata et al. (2017)

### Study size, design and location

A 2-phase comparative study at 3 dialysis centres of 232 people having dialysis with tunnelled catheters in the US.

### Intervention and comparator

Intervention: Tegaderm CHG dressing.

Comparator: Adhesive dry gauze dressing.

### Key outcomes

In phase 1, catheter-related infection rates per 1,000 days at the dialysis centre that switched to using the Tegaderm CHG dressing reduced by 52% (1.69 compared with 0.82 infections per 1,000 days; $p<0.05$) compared with the pre-intervention period. In phase 2, when the Tegaderm CHG dressings were then introduced at the 2 sites that had been using the comparator, catheter-related infection rates reduced by 86% (1.86 compared with 0.26; $p<0.05$) and 53% (1.89 compared to 0.88; $p<0.05$) compared with phase 1.

### Strengths and limitations

The demographics of the people in the haemodialysis units were comparable between centres. The catheter-related infection rates were not statistically different during the 12-month pre-intervention period or during the 12-month period when all centres used the Tegaderm CHG dressing. However, this study was not blinded and the change to dressing protocol could have led to improved adherence and so fewer infections. This study was not done in the UK.

## Righetti et al. (2016)

### Study size, design and location

A randomised crossover study of 59 adults having dialysis with a tunnel central venous catheter in Italy. Patients had treatment for 6 months, then were switched for the next 6 months.

### Intervention and comparator

Intervention: Tegaderm CHG dressing.

Comparator: Standard polyurethane dressing.

### Key outcomes

The catheter-related infection rate per 1,000 catheter days was reduced from 1.21 with a standard dressing to 0.28 with Tegaderm CHG (p=0.02). The catheter-related bloodstream infection rate per 1,000 catheter days was 0.09 with Tegaderm CHG and 0.65 with a standard dressing (p=0.05).

### Strengths and limitations

This study had similar demographics between treatment groups. There was no wash-out period with the intervention switch, which could have affected infection rates in both groups. This study was not done in the UK.

## Düzkaya et al. (2016)

### Study size, design and location

A randomised controlled, single-centre study of 100 children in a paediatric intensive care unit in Turkey.

### Intervention and comparator

Intervention: Tegaderm CHG dressing.

Comparator: Standard sterilised dressing.

### Key outcomes

There was no significant difference in local catheter infection, CRBSI, colonisation or contamination rates between the 2 groups.

### Strengths and limitations

This was a randomised controlled trial with blinding in the interpretation of microbiological results. The patient demographics between the groups were similar. This study was not done in the UK and the dressings were replaced daily.

## Ergul et al. (2018)

### Study size, design and location

A prospective, comparative, single-centre study of 131 children in a paediatric intensive care unit in Turkey. The inclusion criterion was jugular vein catheterisation for 48 hours or more.

### Intervention and comparator

Intervention: Tegaderm CHG dressing.

Comparator: Transparent polyurethane film dressing.

### Key outcomes

There were no statistically significant differences in CRBSI rates between the intervention and control group.

### Strengths and limitations

The demographics were similar between the study groups. The Tegaderm CHG dressing was left for 5 to 7 days (or changed as needed) in line with the instructions for use. The standard dressing was changed every 2 days, which may have limited the risk of infection.

This study had a small sample size, which may have limited the power to detect significant changes, and it was not randomised.

## Madeo and Lowry (2011)

### Study size, design and location

A prospective audit of 138 people receiving total parenteral nutrition via a venous access device.

### Intervention and comparator

Intervention: Tegaderm CHG dressing.

Comparator: Standard vapour-permeable film dressing.

### Key outcomes

The average length of total parenteral nutrition was 10 days. CRBSI reduced from 8 to zero when dressings were switched to Tegaderm CHG, but this was not significant (p=0.057).

### Strengths and limitations

This was a small study with limited outcome measures. The study was done in the UK.

# Sustainability

The company claims to minimise waste and use renewable resources during product manufacture. It is also improving energy efficiency and increasing its use of renewable sources of energy. There is no published evidence to support these claims.

# Recent and ongoing studies

No relevant ongoing or in-development trials were identified.

# Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 experts were familiar with or had used this technology before.

## Level of innovation

All the experts said that the technology was innovative because it is the only dressing that contains chlorhexidine gluconate (CHG) in the gel pad. They also noted that the dressing was transparent, unlike some others, which allows catheter exit site monitoring.

## Potential patient impact

All the experts said that Tegaderm CHG IV securement dressing reduces the risk of exit site infections. One expert also commented on the continuous release of CHG for up to a week, a potential reduction in antibiotic exposure and hospitalisation because of the lower infection risk, and fewer tunnel infections and resulting catheter exchanges. One expert noted that Tegaderm CHG could benefit all long-term vascular catheter users and another said it could benefit all people with a central venous catheter. Another expert suggested that Tegaderm CHG is best used in people at higher risk of infection or with short, non-tunnelled acute central venous catheters in the internal jugular or subclavian vein. The experts also said that people with peripherally inserted central catheter (PICC) lines and tunnelled catheters are at a lower risk of exit site infection and may not need a CHG dressing if the site is well maintained.

## Potential system impact

One expert said that reduced patient morbidity and mortality due to catheter-related infections is the most important outcome for Tegaderm CHG. They also said that it could save the NHS costs associated with replacement catheters, catheter re-insertion, hospitalisation for sepsis, lost dialysis or treatment sessions, and reduced antibiotic use.

Another expert agreed that Tegaderm CHG could be cost saving by reducing the need to treat catheter-related bloodstream infections (CRBSI). One expert suggested it would cost

more than using a standard intravenous dressing alongside good care and maintenance regimes. All the experts noted that no changes to facilities and infrastructure are needed, and minimal training is needed. All the experts highlighted the potential risk of allergy to the dressing.

## General comments

One expert said that CHG dressings should only be used if there is a history of skin infections leading to exit site infections. They also said that this dressing protects the exit site of the catheter but not against CRBSI from the lumen. However, another expert has adopted this dressing as standard care in dialysis treatment and found that it led to fewer exit site infections. One expert said that Tegaderm CHG has been well received by their patients having haemodialysis.

# Expert commentators

The following clinicians contributed to this briefing:

- Dr Anuradha Jayanti, consultant nephrologist, Manchester Royal Infirmary. No conflicts declared.
- Mr Andrew Barton, advanced nurse practitioner, Frimley Heath NHS Trust. Mr Barton has received an honorarium as a speaker at the UK and Ireland IV Leadership Summit.
- Ms Jackie Nicholson, nurse consultant in vascular access, St George's University Hospital NHS Trust. Ms Nicholson has been involved in speaking engagements for 3M related to vascular access but has not been involved in marketing this product.

# Development of this briefing

This briefing was developed by NICE. NICE's interim process and methods statement for the production of medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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