NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

Leukomed Sorbact for preventing surgical site infection

The National Institute for Health and Care Excellence (NICE) is producing guidance on using Leukomed Sorbact for preventing surgical site infection in the NHS in England. The medical technologies advisory committee has considered the evidence submitted by the company and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence (see the committee papers).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and resource savings reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Note that this document is not NICE's final guidance on Leukomed Sorbact for preventing surgical site infection. The recommendations in section 1 may change after consultation.

After consultation the committee will meet again to consider the evidence, this document and comments from the public consultation. After considering the comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England. For further details, see the medical technologies evaluation programme process and methods guides.

The key dates for this guidance topic are:

Closing date for comments: 23 October 2020

Second committee meeting: 13 November 2020

Details of the advisory committee are given in section 5.

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 Evidence supports the case for adopting Leukomed Sorbact for closed surgical wounds after caesarean section and vascular surgery in the NHS.

1.2 Leukomed Sorbact should be considered as an option for people with wounds that are expected to have low to moderate exudate. It should be used as part of usual measures to help reduce the risk of surgical site infections.

1.3 Cost modelling shows that the reduced rate of surgical site infections with Leukomed Sorbact compared with standard surgical dressings leads to savings of:

- £107.43 per person after caesarean section
- £17.82 per person after vascular surgery.

By adopting this technology, the NHS may save up to £860,000 per year for caesarean section and up to £14,000 per year for vascular surgery. For more details, see the NICE resource impact report.

Why the committee made these recommendations

Leukomed Sorbact is an interactive dressing that binds to the microbes that cause surgical site infections so they are removed when the dressing is changed.

Evidence suggests that using Leukomed Sorbact instead of standard dressings after caesarean section and vascular surgery reduces the rate of surgical site infections and leads to cost savings. So Leukomed Sorbact is recommended for wounds expected to have low to moderate exudate.

2 The technology

Technology

2.1 Leukomed Sorbact (Essity), is a sterile, single-use, bacteria-binding, adhesive-bordered wound dressing. It is used to prevent surgical site

infection (SSI) in closed surgical wounds that have low to moderate exudate.

2.2 The dressing comprises an absorbent non-woven wound contact pad and an outer transparent adhesive polyurethane film. The pad is made of a white viscose polypropylene and polyester mesh that is coated with the proprietary compound dialkylcarbamoyl chloride (DACC). DACC is hydrophobic, meaning that it does not mix with water and tends to bind to itself or other hydrophobic materials if water is present. In a moist wound environment, DACC binds to hydrophobic bacteria and fungi that cause SSIs. These bound microorganisms are then removed from the wound site when the dressing is changed. The DACC binding does not cause bacteria to be lysed (broken open), which avoids causing inflammation at the wound site. The polyurethane film is designed to maintain a moist environment and protect the wound from external contamination. The dressing is available in various sizes.

Innovative aspects

2.3 The innovative aspect is the DACC component. This binds and inactivates bacteria through hydrophobic interaction, which helps to reduce colonisation of the wound by potentially harmful microbes.

Intended use

2.4 Leukomed Sorbact is intended to be applied by a surgeon or theatre nurse in the operating theatre after surgery. It can also be used in the early post-operative period when the dressing needs to be replaced.

Costs

2.5 The cost of Leukomed Sorbact is £9.15 per dressing (excluding VAT). There are no other costs for implementing this technology and no training costs. For more details, see the website for Leukomed Sorbact.

3 Evidence

Clinical evidence

The relevant clinical evidence consists of 5 studies, including 3 randomised trials

3.1 The external assessment centre (EAC) considered 5 publications:

- 1 randomised controlled trial (RCT; Stanirowski et al. 2016a)
- 2 pilot RCTs (Totty et al. 2019; Stanirowski et al. 2016b)
- 1 non-RCT (Bua et al. 2017) and
- 1 unpublished audit (Taylor et al. 2020).

The EAC excluded 5 studies identified by the company because 4 did not include Leukomed Sorbact and there were significant uncertainties about the design of 1 study.

The evidence considered is limited to caesarean section and vascular surgery

3.2 Stanirowski et al. 2016a and 2016b were both done in Poland in women having elective or emergency caesarean section. Totty et al. 2019 and Bua et al. 2017 were UK studies in people having vascular surgery. [redacted].

The evidence suggests Leukomed Sorbact reduces SSIs in caesarean section and vascular surgery

3.3 Up to 30 days after surgery, surgical site infection (SSI) rates were lower for people having Leukomed Sorbact compared with those having standard dressings. The difference in infection rates was not always statistically significant depending on the trial size. The largest RCT, considered to have the least risk of bias (Stanirowski et al. 2016a), reported a SSI rate of 1.8% for people having Leukomed Sorbact after caesarean section, and 5.2% for those having standard dressings at 14 days (statistically significant, p=0.04). Stanirowski et al. 2016b reported

a SSI rate of 2.8% for people having Leukomed Sorbact after caesarean section, compared with 9.8% for those having standard dressings at 14 days (p=0.08). Bua et al. 2017 reported a SSI rate of 1% for Leukomed Sorbact and 10% for standard dressings at 5 to 7 days (statistically significant, p<0.05). Totty et al. 2018 and Bua et al. 2017 reported SSI rates of 16% and 9% at 30 days respectively for people having Leukomed Sorbact after vascular surgery, compared with 26% and 20% for standard dressings. The differences were not statistically significant (p=0.161 and p=0.83, respectively).

The evidence suggests that Leukomed Sorbact may reduce antibiotic use

3.4 In 3 studies there was less need for antibiotic treatment with Leukomed Sorbact compared with standard dressings (Bua et al. 2017, Stanirowski et al. 2016a and 2016b). In all studies the numbers reported as having antibiotics were low in both arms, and the reported differences were not statistically significant in Stanirowski et al. 2016a (0 in Leukomed Sorbact group, 4 in control group, p=0.13).

The evidence suggests that Leukomed Sorbact may reduce readmissions from wound complications

3.5 Stanirowski et al. 2016a reported that people with a SSI in the standard dressings group each had 2.9 outpatient hospital visits. People with a SSI in the Leukomed Sorbact group had 4.6 visits, a difference that was statistically significant, p=0.02. However, this was a secondary analysis in a small subgroup of patients. The same study found fewer additional days

in hospital in people having Leukomed Sorbact (0 days compared with 8.2 days for standard dressings, p=0.22).

Cost evidence

The published economic evidence suggests Leukomed Sorbact is cost saving

3.6 The economic analysis in the Stanirowski et al. 2016a and Stanirowski et al. 2019 studies showed that Leukomed Sorbact is cost saving when compared with standard surgical dressings. Stanirowski et al. 2016a reported total costs for preventing and treating SSIs of 5,775 euros in the standard care group compared with 1,065 euros in the Leukomed Sorbact group. Stanirowski et al. 2019 used the same data and applied a decision-analytic model from a UK NHS perspective. This showed a cost saving of £119.07 per patient in favour of Leukomed Sorbact.

The company's cost modelling finds Leukomed Sorbact to be cost saving for caesarean section, vascular surgery and all surgery

3.7 The company submitted a simple decision tree model with 2 interventions, Leukomed Sorbact or standard surgical dressings. There were 2 outcomes, SSI or no SSI. The time horizon was 30 days. The company reported base-case cost savings per person with Leukomed Sorbact of £107.43 for caesarean section, £23.55 for vascular surgery, and £20.56 for all surgery. The company's sensitivity analyses found these results to be robust to parameter changes.

The EAC agrees with the company's cost model but disagrees about including all surgery because of lack of evidence

3.8 The EAC agreed with the company's model and its assumptions and made 1 change, to the cost of an SSI episode for vascular surgery. Leukomed Sorbact remained cost saving but the cost savings were lower than those estimated by the company's model for vascular surgery, at £17.82 per patient. The cost savings remained robust to parameter changes. The EAC chose not to model the use of Leukomed Sorbact for

all types of surgery because it considered that there was insufficient clinical evidence to do so.

4 Committee discussion

Clinical-effectiveness overview

Leukomed Sorbact reduces SSIs after caesarean section

4.1 The committee noted that Stanirowski 2016a was a well performed randomised controlled trial (RCT) with a limited risk of bias. The results showed a statistically significant reduction in surgical site infection (SSI) at 14 days in people having Leukomed Sorbact compared with standard dressings. The committee and clinical experts discussed the relatively low rate of systemic antibiotic use in people who had SSIs in this study. The committee considered that this was likely to be explained by the infections being relatively mild. The clinical experts stated that intravenous antibiotics were only needed for treating the most severe SSIs. The committee concluded that the evidence suggested that using Leukomed Sorbact reduces the rate of SSIs after caesarean section compared with standard dressings.

Leukomed Sorbact reduces the incidence of SSIs after vascular surgery

4.2 The prospective non-randomised Bua et al. study showed that there were fewer SSIs in people who had Leukomed Sorbact compared with those who had standard dressings at 5 to 7 days and at 30 days. Although the number of people included in the Totty et al. pilot RCT was relatively small, there were fewer SSIs in the people who had Leukomed Sorbact. Overall, the committee concluded that the study results and the plausibility

of the clinical benefit for this group was sufficient to support the use of Leukomed Sorbact after vascular surgery.

The evidence does not support a broader recommendation to use Leukomed Sorbact in all types of surgery

4.3 No evidence was presented to support the use of Leukomed Sorbact in surgery other than caesarean section and vascular surgery. It was noted that Leukomed Sorbact could potentially be particularly useful in plastic surgery and breast surgery, which involve subcutaneous dissection. One clinical expert stated that Leukomed Sorbact is currently being used after gynaecological surgery at their hospital but there are no data currently available on this use. The committee concluded that the current evidence could not be extrapolated to support the use of Leukomed Sorbact after all types of surgery. It also concluded that it would welcome further research on the use of Leukomed Sorbact in other types of surgery.

Feedback from clinical experts was positive

4.4 Comments from clinical experts about the clinical benefits of Leukomed Sorbact were positive, noting that it seemed to reduce SSIs and was easy to use. The clinical experts were broadly optimistic that Leukomed Sorbact may be useful for other types of surgery.

Other patient benefits or issues

Using Leukomed Sorbact to reduce SSI risk after caesarean section may enhance recovery

4.5 In Stanirowski 2016a, developing SSI led to an increase in mean hospital stay of 8.2 days and an increase in mean outpatient visits from 2.9 to 4.6 per person in the Leukomed Sorbact group. The clinical experts explained that reducing SSIs may have additional benefits, such as new mothers being able to care for their babies and a positive effect on postnatal mental health. The committee concluded that reducing the incidence of

SSIs after caesarean section was likely to reduce the need for prolonged hospital stays and enhance recovery.

Compared with PICO negative pressure wound therapy, Leukomed Sorbact is comfortable and discreet

4.6 The clinical experts reported that people using Leukomed Sorbact had found it to be comfortable and had positive feedback. Unlike the battery powered PICO, it can be worn while showering and does not make any noise.

Side effects and adverse events

Leukomed Sorbact has only uncommon, minor adverse events

4.7 The clinical experts noted only 1 report of contact dermatitis after the use of Leukomed Sorbact. The external assessment centre (EAC) identified 1 adverse event registered with the US Food and Drug Administration, in which a person who had a total knee replacement developed a chemical burn after using Leukomed Sorbact. About 1 month after surgery, the person attended the emergency department because of a chemical burn with eschar over the surgical site. The eschar was surgically removed and the person was discharged after 2 days. This was described in the report as a 'device malfunction' but no other details were reported. The company's submission included an observational study in a poster presentation (Coldwell et al. 2014) that found 2 hypersensitivity reactions to the adhesive in 55 people who had Leukomed Sorbact in an Australian primary care setting.

Relevance to the NHS

The studies using Leukomed Sorbact are relevant to the NHS

4.8 The Stanirowski 2016a and 2016b studies, which investigated the use of Leukomed Sorbact after caesarean section, were both done in Poland. The clinical experts advised, however, that the care pathway and outcome measures reported in these studies were relevant to an NHS setting. The

2 studies investigating the use of Leukomed Sorbact for vascular surgery (Totty 2019 and Bua 2017) were done in the UK. The committee concluded that the evidence was relevant to the NHS.

NHS considerations overview

Most wounds from vascular surgery and caesarean section are expected to have low to moderate exudate

4.9 The committee was advised that Leukomed Sorbact is indicated when a wound is expected to have low to moderate exudate. The clinical experts advised that this would be most people having caesarean section or vascular surgery. The clinical experts also explained that people with wounds at risk of high exudate could usually be identified at the time of surgery and these people would not have Leukomed Sorbact dressings.

Cost modelling overview

The company's cost model is appropriate for caesarean section and vascular surgery but not for other types of surgery

4.10 The committee agreed with the EAC that the company's cost model was appropriate for analysing the costs of using Leukomed Sorbact after caesarean section and vascular surgery. It noted that only small adjustments were needed. The committee also agreed with the EAC that cost modelling was inappropriate for an all surgery group because there was no evidence to support the benefits of Leukomed Sorbact for all types of surgery.

The EAC's base-case analysis shows Leukomed Sorbact is cost saving

4.11 The EAC's base-case analysis showed that after caesarean section, using Leukomed Sorbact is cost saving by £107.43 per person. After vascular surgery, Leukomed Sorbact is cost saving by £17.82 per person compared with standard dressings. The standard surgical dressing used as the comparator in the cost modelling was the Opsite Post-OP dressing, the best-selling vapour-permeable adhesive film and absorbent sterile pad

dressing. The clinical experts confirmed that this standard dressing was widely used in NHS practice.

The sources for the baseline risk of SSI and the costs of treating SSI after caesarean section and vascular surgery are appropriate

4.12 In the company's model, baseline SSI risks for different surgical indications were taken from NHS England or NHS Wales data. The Leukomed Sorbact SSI risk was taken from the pooled results of the clinical studies (Stanirowski 2016a and 2016b for caesarean section; Bua et al. 2017 and Totty et al. 2019 for vascular surgery). The EAC considered the data sources for these inputs appropriate. The cost of SSI in caesarean section was taken from Jenks 2014. The cost of SSI in vascular surgery was taken from an unpublished study (York Health Economics Consortium 2020) but the EAC considered that costs from Jenks 2014 were more appropriate. The committee accepted that these sources were appropriate.

Main cost drivers

The company's sensitivity analyses show that the cost saving with Leukomed Sorbact is robust

4.13 The company's sensitivity analyses varied the rate of SSIs and the costs of Leukomed Sorbact and the comparator. Leukomed Sorbact remained cost saving in all these analyses. The company did 1-way sensitivity analysis on the cost per SSI episode, varying the cost estimates within their 95% confidence intervals:

- For caesarean section, the base-case SSI episode cost was £4,048 and the breakeven point was £350.
- For vascular surgery, the base-case SSI episode cost was £3,427 and the breakeven point was £2,000.

A second sensitivity analysis investigated the effect of reducing the standard dressing cost by 50% and increasing the cost of Leukomed

Sorbact by 100%, or both. For both caesarean section and vascular surgery Leukomed Sorbact remained cost saving.

The company's scenario analysis reports the breakeven points for reducing SSI risk

4.14 The company did a scenario analysis, varying the relative risk reduction by plus or minus 25%:

- For caesarean section, the base-case SSI risk was 4.35%, with a relative risk reduction of 67% and an incremental cost per person of -£107.43. The breakeven point for relative risk reduction was 6%.
- For vascular surgery, the base-case SSI risk was 2.5%, with a 42% relative risk reduction and an incremental cost per person of -£23.54. The breakeven point for relative risk reduction was 13%.

The EAC's threshold analyses estimate the breakeven points in the cost model

4.15 The EAC did threshold analyses for cost savings from using Leukomed Sorbact after caesarean section and vascular surgery. The breakeven points were estimated for key values in the cost model. For caesarean section:

- Baseline SSI risk: base case 4.35%, breakeven point 0.39%.
- Relative risk reduction in SSI: base case 67%, breakeven point 6%.
- SSI episode cost: base case £362, breakeven point £4,048.

For vascular surgery:

- Baseline SSI risk: base case 2.5%, breakeven point 0.93%.
- Relative risk reduction in SSI: base case 42%, breakeven point 16%.
- SSI episode cost: base case £2,072, breakeven point £1,004.

Leukomed Sorbact is cost saving across a wide range of values for SSI costs, device costs, comparator costs and relative risk reduction

4.16 There were wide margins for cost neutrality and cost savings. This satisfied the committee that even with some uncertainty around the strength of the clinical evidence, Leukomed Sorbact was highly likely to be cost saving in caesarean section and vascular surgery.

Further research

Further research on Leukomed Sorbact would be welcome

4.17 The committee noted that that a multicentre RCT on the use of Leukomed in vascular surgery is being proposed and it welcomed this. In addition, it encouraged further research on using Leukomed Sorbact for a wider range of surgical indications, as well as investigating the effect of Leukomed Sorbact on people with different baseline SSI risks.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technology advisory committee which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

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

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

Neil Hewitt, Rebecca Owens, Harriet Unsworth
Technical analysts

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