NICE National Institute for Health and Care Excellence

NICE guidance

Topical antimicrobial dressings for locally infected leg ulcers: late-stage assessment

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces HTE27.

1 Recommendations

1.1 There is not enough evidence to determine whether price variations are justified between different antimicrobial agents in topical antimicrobial dressings for locally infected leg ulcers.

1.2 NHS trusts should provide access to a range of different types of antimicrobial dressings, so that a product that is clinically appropriate and meets people's needs is available for everyone with locally infected leg ulcers.

1.3 A healthcare professional and the person with the leg ulcer should decide together which dressing to use (see the NICE page on shared decision making). Decisions should take into account how the choice of dressing might affect the person's quality of life, including:

- physical health
- mental health and wellbeing
- relationships with others
- ability to complete activities of daily living.

1.4 If an antimicrobial dressing is needed to treat a locally infected leg ulcer, use a clinically appropriate dressing that meets the needs and preferences of the person with the leg ulcer, and if more than 1 is appropriate, choose the least expensive option. Include the following factors when choosing a dressing:

- the cost of the primary dressing
- the need for and cost of additional products
- the frequency of dressing changes needed
- if a person can change their own dressing or if a visit by a healthcare professional is needed.

What information is needed

More information is needed to determine whether price variations are justified between different antimicrobial agents in topical antimicrobial dressings for locally infected leg ulcers. Evidence should compare agents with each other and in similar dressing types. Evidence should be statistically powered, report details of concomitant treatments and ideally be done in a community setting in the NHS.

Key outcomes that should be captured include:

- clinical performance outcomes of the dressings to evaluate clinical and cost effectiveness, including:
  - health-related quality of life
  - time taken to clear signs and symptoms of wound infection
  - time to complete wound healing
  - duration of antimicrobial dressing use and any other leg ulcer treatments
  - short- and long-term toxicity of the antimicrobial agents in the dressings
  - other adverse events or sensitivities to the dressing, including the number of people who have contraindications to particular antimicrobial agents
  - infection load and the type of bacteria killed or removed by the dressing
  - the number of people progressing to escalation of care and any associated resource costs
- healthcare professional preferences, including:
  - dressing conformability
  - ease of application
  - ease of removal.

What this means in practice

Considerations for procurement and commissioning

- Leg ulcers are the most common chronic wound in the UK. Estimates of the associated healthcare costs range from £102 million (Urwin et al. 2022) to £3.2 billion per year (Guest et al. 2020). The annual amount of NHS resource spent on dressings for venous leg ulcers was estimated at nearly £80 million (Guest et al. 2020).
- Many factors can influence which type of topical antimicrobial dressing is best to treat a locally infected leg ulcer. Commissioners and procurement specialists should work with healthcare professionals in NHS trusts to ensure access to an appropriate range of topical antimicrobial dressings.
- If a company introduces a new antimicrobial dressing or a new dressing feature with a higher price to market, they should provide evidence to justify price variation.

Considerations for wound management formulary groups

- These recommendations are not intended to restrict choice. When developing a formulary, if dressings have similar technical specifications but different agents or prices, decision making should consider cost and the factors listed in recommendation 1.4.
- Information on the cost of dressings should be available to healthcare professionals so that they can decide, using the factors listed in recommendation 1.4, which of the clinically appropriate options is the least expensive.

Considerations for healthcare professionals

- These recommendations do not replace clinical reasoning. If more than one type of dressing is clinically appropriate, the choice of dressing should be based on patient preferences and cost, taking into account the factors listed in recommendations 1.3 and 1.4.

- Healthcare professionals should work with commissioners and procurement specialists who cover their NHS trust to ensure access to an appropriate range of antimicrobial dressings.

Considerations for people with locally infected leg ulcers

- People with locally infected leg ulcers should be involved when deciding which antimicrobial dressing to use. They should be given information on the antimicrobial dressing that is being prescribed and, where possible, offered options that meet their needs.
- People with locally infected leg ulcers should be given support if they have any issues and wish to change to another type of antimicrobial dressing.

NICE has produced tools and resources to support the implementation of this guidance.

Why the committee made these recommendations

There are many topical antimicrobial dressings available for locally infected leg ulcers, with a variety of antimicrobial agents that vary in technical specification and cost. This assessment aims to determine whether the differences in clinical, economic and non-clinical outcomes attributed to those antimicrobial agents could justify price variation.

Because of uncertainties in the clinical evidence, it is not possible to say whether any antimicrobial agent works better than the others. These uncertainties include:

- a lack of direct comparisons of antimicrobial agents
- differences in:
  - the outcomes measured and
  - when the outcomes were measured.

More evidence is needed on how well different antimicrobial dressings work before it would be possible to say whether price differences are justified.

Evidence shows that people with locally infected leg ulcers are often not involved in selecting their antimicrobial dressing. There are many quality-of-life factors that could be impacted by using an antimicrobial dressing and these should be discussed with the person when choosing a dressing.

2 The technology

2.1 Topical antimicrobial dressings are dressings that aim to decrease the microbial burden of the wound. How they work varies, with some dressings designed to release the antimicrobial agent into the wound to kill or inhibit the growth of microorganisms. Other antimicrobial dressings have no active pharmaceutical component and aim to physically remove microorganisms from the wound. Antimicrobial dressings are one of the options available to healthcare professionals when treating locally infected leg ulcers. There are various types of wound care dressings, with different intended clinical benefits. These are shown in table 1.

Table 1 Types of dressings and their uses

Dressing types	Uses
Alginate, gelling fibre and absorbent fibre	Exuding wounds, to act as an absorbent while maintaining a moist environment (alginates and gelling fibres can also be used to aid debridement of devitalised tissue)
Foams and absorbent pads	Low to high exuding wounds
Wound contact layers, for example gauze	Superficial or partial thickness wounds
Ointments, hydrogels, gels or pastes containing the antimicrobial agent, or ribbons made from one of the materials from another dressing type	Deeper wounds and wounds that need debridement of thick slough
Hydrocolloid	Aiding debridement of devitalised tissue

2.2 As well as different types of dressing, there are different antimicrobial agents used in dressings. These are the focus of this assessment. Chemically or pharmacologically active antimicrobial agents include:

- silver
- chitosan

- honey
- iodine
- copper
- chlorhexidine
- enzyme alginogel
- octenidine and
- polyhexamethylene biguanide (PHMB).

  Nonactive agents with a physical mode of action include dialkylcarbamoyl chloride (DACC).

2.3 Some agents are available in different forms (described as subagents). For example:

- honey:
  - Manuka
  - monofloral
  - polyfloral
- iodine:
  - cadexomer iodine
  - povidone iodine
- silver, the subagents of which can be categorised into 3 groups based on the International Wound Infection Institute consensus update (2022):
  - silver salts and compounds:
    - ionic silver
    - silver sulphate

        - ◇ silver sulphadiazine
        - ◇ silver oxysalts
        - ◇ ionic silver complex
      - elemental silver:
        - ◇ metallic or elemental silver and
        - ◇ nanoparticulate silver and
      - ionic silver with antibiofilm agents
  - copper: cupric oxide.

2.4 There are many antimicrobial dressings available to the NHS. For this assessment NICE considered antimicrobial dressings listed on the NHS Drug Tariff Part IX.

3 Committee discussion

The medical technologies advisory committee considered evidence on antimicrobial agents in topical antimicrobial dressings for locally infected leg ulcers. Evidence was taken from several sources and used to determine whether price variation between agents could be justified by differences in their clinical and cost effectiveness or in non-clinical outcomes important to users. Full details are available in the project documents for this guidance.

The condition

3.1 The National Wound Care Strategy Programme defines a leg ulcer as an ulcer between the knee and ankle that has not healed within 2 weeks. Most leg ulcers are caused by venous insufficiency, although they can also be caused by peripheral vascular disease, reduced mobility, cardiac failure, diabetes or sickle cell disease. Prevalence estimates for leg ulcers vary across the literature. For example, estimates for venous leg ulcers range from a point prevalence of 0.03% (Urwin et al. 2022) to an estimated annual prevalence of 1.08% (Guest et al. 2020). The focus of this assessment is the subset of leg ulcers with a local infection. The prevalence of infection in both leg ulcers of any cause and venous leg ulcers was reported to be 18% (Vowden and Vowden 2009) and 41% (Guest et al. 2020) respectively. Ulcers heal slower when they are infected. Leg ulcers can show signs and symptoms of local infection. The International Wound Infection Institute defines these as either covert or overt. Covert signs and symptoms include:

- hypergranulation
- bleeding or friable granulation
- epithelial bridging and pocketing in granulation tissue
- increasing exudate and
- delayed wound healing beyond expectations.

Overt signs and symptoms include:

- erythema
- local warmth
- swelling
- purulent discharge
- wound breakdown and enlargement
- new or increasing pain and
- increasing malodour.

Leg ulcers can also show signs and symptoms of spreading and systemic infection. People with leg ulcers with a spreading or systemic infection are outside the scope of this late-stage assessment.

Current practice

3.2 The management of infected leg ulcers is described in the NICE guideline on leg ulcer infection: antimicrobial prescribing. This recommends that an antibiotic is offered when there are symptoms or signs of infection (for example, redness or swelling spreading beyond the ulcer, localised warmth, increased pain or fever). In clinical practice, antimicrobial dressings can be used to treat leg ulcers that have signs and symptoms of local infection. The choice of dressing is informed by the wound presentation and the person's individual needs. So, dressing choice often changes throughout the duration of a wound. In general, a dressing should be used for no more than 2 weeks before the wound and dressing are reassessed. Subsequent dressings may be of the same type or there could be a step down to a nonantimicrobial dressing or step up to a second-line option. If there is still evidence of local infection after 2 weeks, further escalation for advice from the tissue viability team may be necessary, depending on local guidance. There is no national guidance on using topical antimicrobial dressings to treat locally infected leg ulcers. This has led to the development of local guidance within formularies (where these exist), and a wide variation in practice and available dressings across the NHS. Other measures aimed at treating locally

infected leg ulcers include compression, systemic antimicrobial therapy, wound bed preparation and debridement. The committee discussed shared care and heard from clinical experts. They noted that decisions on shared care are always situation-specific and should be made collaboratively between the healthcare professional and the person with the locally infected leg ulcer.

Lived experience

3.3 A survey of people with locally infected leg ulcers showed that most respondents (10 out of 12) reported that they were not involved in the decision making process to select an antimicrobial dressing. The committee heard from a patient expert how using an antimicrobial dressing for an infected chronic surgical wound had impacted their life. They explained that the dressing caused discomfort and embarrassment, and that there was sometimes a smell from the infected wound. Using the dressing had also had a negative impact on their mental health and their relationships. They also described the lack of shared decision making when being prescribed an antimicrobial dressing. The committee acknowledged that the patient expert had used antimicrobial dressings for an infected surgical wound and not an infected leg ulcer. But, it agreed that a wound infection could have a significant impact on a person's health and quality of life. Clinical experts told the committee that the themes of the lived experience testimony align with their experience of treating leg ulcers. But, the clinical experts acknowledged that there may be different considerations for people with chronic, as opposed to nonchronic, leg ulcers. The committee concluded that a shared decision should always be made, and that the impact of the dressing selection should be considered when deciding which antimicrobial dressing to use.

Healthcare professional preferences

3.4 The committee considered evidence from a user preference assessment completed by healthcare professionals. The assessment aimed to explore which criteria are most important to healthcare professionals when choosing an antimicrobial dressing for a locally infected leg ulcer. This included all aspects of an antimicrobial dressing and not just the antimicrobial agent. Healthcare

professionals were selected for the user preference assessment because, although shared decision making is promoted and patient preference is considered, the choice of dressing is ultimately made by the healthcare professional. The group comprised 15 healthcare professionals who had experience of prescribing antimicrobial dressings. The group developed 2 sets of criteria for selecting a dressing. These were criteria based on clinical presentation, which included a holistic assessment of the person's clinical and social needs, and criteria that are independent of clinical presentation.

Criteria based on clinical presentation

3.5 The group identified 5 main criteria related to clinical presentation:

- wound presentation
- medical history and patient characteristics
- previous dressing regimes and efficacy
- mode of action of agent or dressing
- cytotoxicity of antimicrobial agent.

Criteria independent of clinical presentation

3.6 The group also identified 5 criteria that are independent of clinical presentation. Ranked in order of importance, they were:

- conformability
- ease of removal
- application directions
- cost
- sustainability.

Conformability was defined by the group as how conformable the dressing is to the shape of the leg (anatomical landscape) and how well it stays fixed to the site after it has been placed. None of these criteria are specific features of individual branded dressings or antimicrobial agents, but are generic and relate to general dressing performance. The committee noted that apart from cost and, to a lesser extent, ease of removal, these preferences are not captured by the evidence. The committee concluded that future evidence collection should evaluate the performance of dressings in these criteria.

Equality considerations

3.7 Many different groups can be affected by locally infected leg ulcers. Some of these groups have protected characteristics. The committee heard that older people are more likely to have a leg ulcer. Also, people from lower socioeconomic groups can have longer healing times with a higher chance of the ulcer recurring. The committee was made aware that the chance of having a leg ulcer is higher in people who are seriously ill, have a neurological condition, impaired mobility, impaired nutrition or obesity. The risk of infection is also higher in people with conditions such as anaemia, cardiac disease, respiratory disease, peripheral arterial disease, diabetes, renal impairment or rheumatoid arthritis. The committee also heard that people from certain ethnic minority backgrounds (South Asian, Chinese, Black African and Black Caribbean) have an increased risk of diabetes, which increases the risk of infection. Leg ulcers are also more common in people with haemoglobinopathies such as sickle cell disease and thalassaemia. Signs of infection may also be less visible on darker skin. The committee also heard that some conditions, such as diabetes, can make the signs and symptoms of infection less obvious. The committee was made aware that smoking, dependence on alcohol, drug use and nutritional deficiencies can be contributing factors to delayed wound healing. When people are less adherent to their treatment plan, they can be at a higher risk of developing an infection. The committee heard that this may be a risk for people with mental health conditions and learning disabilities. When discussing access to services, the committee heard that people with no fixed address may experience difficulties if they need frequent dressing changes. The committee was made aware that while some of the antimicrobial agents in scope contained animal products, some do

not and can be used by people in all faith groups and by vegans. The committee also heard that some dressings and agents may not be suitable during pregnancy or while breastfeeding (some nonactive agents may be suitable), or for people with thyroid dysfunction. The committee understood that people who have locally infected leg ulcers will have individual needs and that these should be considered when selecting an antimicrobial dressing.

Clinical effectiveness

Key evidence is limited

3.8 The evidence for antimicrobial dressings to treat locally infected leg ulcers is heterogeneous and limited in quality. The evidence base is predominantly in adults. The EAG could not determine the relative efficacy of the different antimicrobial agents, despite there being an indication of some benefits in treating infection and wound healing. It identified 35 studies for inclusion in the review. But not all of these were in people with locally infected leg ulcers. If there was no evidence for an antimicrobial agent in people with locally infected leg ulcers, the EAG included studies in people with infected wounds elsewhere on the body. If there was still no evidence for the agent, the EAG included studies in people with leg ulcers that were not infected or where the infection status was unclear. This allowed the EAG to evaluate all but 1 of the agents (no evidence was identified for chlorhexidine) but meant that some evidence was less generalisable to people with infected leg ulcers. Of the 35 studies, 22 were in people with infected leg ulcers. Of these, 19 evaluated silver, 2 iodine, 1 octenidine, 1 dialkylcarbamoyl chloride (DACC) and 2 honey (some studies evaluated more than 1 agent). There were 8 studies in people with infected wounds that were not leg ulcers. Of these, 1 evaluated DACC, 2 honey, 3 enzyme alginogel and 2 chitosan. There were 5 studies in people with leg ulcers that were not infected or where the infection status was unclear. Of these, 2 evaluated polyhexamethylene biguanide (PHMB) and 3 evaluated copper. There was evidence in:

- 2 of the 3 subagents of honey (Manuka and monofloral)
- 1 of the 2 subagents of iodine (cadexomer iodine)

- the following 7 of the 8 subagents of silver:
  - ionic silver with antibiofilm agents
  - ionic silver
  - silver sulphate
  - silver sulphadiazine
  - metallic or elemental silver
  - silver oxysalts and
  - ionic silver complex
- the subagent of copper (cupric oxide).

No evidence was available for polyfloral honey, povidone iodine or nanoparticulate silver. There was no evidence available for any population subgroups such as type of leg ulcer or wound presentation.

Additional limitations of the evidence

3.9 There is limited evidence comparing the effectiveness of the different agents in the relevant outcomes. Most outcomes were not well reported or were measured using different tools across studies, making it difficult to draw conclusions from the data. Key outcomes with the most evidence were infection status, complete or partial wound healing and change in size or area of ulcer or wound. Minimal quality-of-life data was found. The included studies varied in design and healthcare setting. Only 8 of the studies were done at least partially in the UK, so the evidence is less generalisable to the NHS. The studies also lack statistical power and agents were not compared in similar types of dressing. The EAG found most studies in people with infected leg ulcers have a moderate to high risk of bias. The committee concluded that there was not enough evidence to make conclusions on the relative performance of the different agents and subagents in all outcomes.

Cost effectiveness

Model structure

3.10 The EAG developed a Markov model that included 4 health states:

- infected, unhealed wound
- noninfected, unhealed wound
- healed wound
- death.

The EAG compared 6 agents with each other in a fully incremental analysis and a pairwise analysis between agents. These were iodine, copper, chitosan, silver, honey and PHMB. There was not enough evidence available to include chlorhexidine, enzyme alginogel, octenidine or DACC in the analysis. Subanalyses were done using the same methods to compare relevant subagents with each other. The results of the main and subanalyses were presented as total costs and associated quality-adjusted life years (QALYs). The EAG used a 1-year time horizon with a 1-week cycle length.

Model inputs

3.11 The EAG's model included parameters of clinical performance, resource use and dressing costs. It used the evidence identified in the review for clinical performance, other published literature for resource use, and the NHS Drug Tariff Part IX and registry data for the dressing costs. Because of the limited evidence, and to avoid assuming clinical equivalence of different antimicrobial agents, the EAG made the following assumptions to inform parameters:

- the rate of complete healing was used to estimate:
  - a per-week healing rate and
  - the rate of infection resolution

- after their first-line antimicrobial dressing, people progressed to a weighted second-line 'basket' of treatments that were assumed to be clinically equivalent regardless of the first-line treatment used
- the leg ulcer infection did not recur within the 1-year time horizon
- the 'infected, unhealed' health state had more per-person dressing changes than the 'noninfected, unhealed' health state
- people in the 'infected, unhealed' and the 'noninfected, unhealed' health states need the same amount of resources
- once in the 'healed' health state it was assumed that there was no resource use, so no costs were associated with this health state.

  The EAG did scenario analyses to explore these assumptions. The clinical experts advised that discontinuation from antimicrobial dressings was considered best practice once an infection had resolved. The clinical experts also advised that linking the rate of infection resolution to complete healing has limitations but that another more appropriate alternative was not available. The committee agreed that to avoid assuming clinical equivalence, and given the lack of better options, the EAG's approach was acceptable.

3.12 Costs of antimicrobial dressings were sourced from Part IXA of the Drug Tariff. A weighted average cost of all dressings containing the agent or subagent was calculated using registry data. The clinical experts advised that costs may vary between acute and community care because of variation in modes of procurement, such as bulk billing, that can be used by acute trusts. The committee felt that costs may not be accurately captured in the model because of variation in procurement packages that can influence the amounts paid by individual trusts or integrated care boards. This is because of the different models of delivery between services, which make it difficult to capture overall costs and spending nationally. The committee also noted that healthcare professionals may be unaware of the costs of dressings. The committee emphasised that cost information should be made more readily available to healthcare professionals through formularies. This would help when deciding which clinically appropriate dressing to use.

Model limitations and scenario analyses

3.13 The committee felt that there were several limitations in the model. These were caused by the uncertainty in, or the lack of, available data to inform the parameters and the assumptions that the EAG had to make. So the results from the economic evaluation should be interpreted with caution. The EAG did several additional scenario analyses to explore these uncertainties. They included:

- varying the weighted cost of the antimicrobial dressing per agent to the maximum and minimum possible
- linking healthcare professional visits and associated resource costs to the frequency of dressing changes
- varying the frequency of dressing changes
- aligning the cost of iodine to cadexomer iodine (the base case used povidone iodine cost and cadexomer iodine efficacy)
- varying the resource requirements, costs and utilities of different health states
- assuming clinical equivalence between agents
- applying different rates of infection.

There was not enough evidence to do analysis of any of the subgroups, including:

- type of leg ulcer
- wound presentation
- location of ulcer or
- complexities that may impact the treatment of leg ulcer infections.

Results of the economic evaluation

3.14 Because of the uncertainty in the evidence used to inform it, the results from the

economic model are highly uncertain. The difference in costs and QALYs are small and the 95% confidence intervals overlapped for all agents in both costs and QALYs. So the EAG could not conclude whether there are clinically meaningful differences between the agents. The high level of uncertainty remained for all of the EAG's scenario analyses. It also remained for the analysis of subagents, which compared 2 honey subagents with each other and the 3 subgroups of silver subagents with each other. The cost of a dressing and the effectiveness of a dressing to clear an infection were 2 of the main drivers of cost effectiveness in the model. Prescription duration and the frequency of dressing changes were also drivers of cost effectiveness. Because of the high uncertainty and lack of data, the committee concluded that more evidence was needed to determine if one antimicrobial agent offered more value than another to the NHS. The committee also noted that because of the uncertainty in the clinical evidence informing the economic evaluation, altering the model structure would be unlikely to produce more certain conclusions.

Resource impact assessment

3.15 There is not enough evidence to determine if price variations between agents are justified. Resource impact analysis showed that using clinically appropriate but less expensive options could make savings for the NHS. The analysis is based on the assumptions used in the EAG's economic model and acknowledges the limitations discussed in the external assessment report. The conclusions of the resource impact analysis are that savings would depend on local current practice, prices being paid, and the considerations for choosing the least expensive option (see recommendations 1.3 and 1.4).

Justification for price variation

3.16 The committee discussed the clinical and economic evidence, the user preference assessment and the patient expert's lived experience. It concluded that it was not possible to determine if the price variation between antimicrobial agents was justified by differences in clinical or cost effectiveness. The committee emphasised that an appropriate range of antimicrobial dressings should be available for healthcare professionals to meet the needs of people with

locally infected leg ulcers.

Evidence needed to show additional value

3.17 The committee concluded that more evidence is needed to justify the price variation between antimicrobial agents used in antimicrobial dressings to treat locally infected leg. It noted that it was not possible to determine the value of individual antimicrobial agents because the available evidence lacked head-to-head comparisons of similar dressings. The committee asked for more evidence using clinical and cost outcomes that can inform a health economic evaluation. It also asked that evidence be collected to evaluate the performance of dressings in the criteria identified in the user preference assessment.

4 Committee members

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

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

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

NICE also recruited clinical experts and specialist committee members for this topic.

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Update information

Minor changes since publication

December 2025: Health technology evaluation 27 has been migrated to HealthTech guidance 751. The recommendations and accompanying content remain unchanged.

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