

UrgoStart for treating diabetic foot ulcers and leg ulcers

Medical technologies guidance

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www.nice.org.uk/guidance/mtg42

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.

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This guidance replaces MIB82.

1 Recommendations

- 1.1 UrgoStart is recommended as a cost saving option to treat diabetic foot ulcers and venous leg ulcers.
- 1.2 There is not enough evidence to support the case for routine adoption of UrgoStart for non-venous leg ulcers.

Why the committee made these recommendations

UrgoStart is a range of dressings which can improve wound healing for diabetic foot ulcers and improve the rate of wound healing for venous leg ulcers. Cost modelling shows that UrgoStart is cost saving compared with standard care dressings in these groups.

UrgoStart should therefore be considered as an option for people with diabetic foot ulcers or venous leg ulcers after any modifiable factors such as infection have been treated.

There is less evidence for non-venous leg ulcers so, although clinical benefits are possible, further evidence is needed to make a recommendation.

2 The technology

Technology

- 2.1 UrgoStart (Urgo Medical) is an interactive dressing for treating diabetic foot ulcers and leg ulcers. It consists of a layer of open-weave polyester mesh impregnated with hydrocolloid polymers within a petroleum jelly known as technology lipido-colloid (TLC). It also contains nano-oligosaccharide factor (NOSF) and has an absorbent pad and a semi-permeable backing.
- 2.2 There are 5 formats of the dressing and each comes in different sizes: UrgoStart Contact Layer, UrgoStart Non-Adhesive, UrgoStart Plus Pad, UrgoStart Border and UrgoStart Plus Border.

Innovative aspects

- 2.3 The TLC-NOSF layer is a combination of the patented TLC technology, which is intended to create a moist protective wound healing environment, and the NOSF, which inhibits protease activity, specifically matrix metalloproteinases, and this is claimed to accelerate healing.

Intended use

- 2.4 UrgoStart is intended for treating chronic wounds. The indications addressed in this evaluation are leg ulcers and diabetic foot ulcers.

Costs

- 2.5 UrgoStart has a typical list price of £4.28 per dressing.

For more details, see the [Urgo Medical website](#).

3 Evidence

Clinical evidence

Relevant evidence comes from 5 studies, 3 of which are randomised controlled trials

- 3.1 Of the 5 studies that met the inclusion criteria defined in the scope, 2 were randomised controlled trials in venous and mixed leg ulcers and 1 was a randomised controlled trial in diabetic foot ulcers. There is also a non-comparative study in diabetic foot ulcers and a pooled analysis of non-comparative observational studies, which included both patient groups. For full details of the clinical evidence, see [section 3 of the assessment report](#).

Results from EXPLORER show an increase in wound closure for diabetic foot ulcers

- 3.2 The multicentre, double-blind, international randomised controlled trial EXPLORER (n=240; 20-week follow-up) compared UrgoStart with UrgoTul, a non-interactive dressing (Edmonds et al. 2018). The results reported a statistically significant increase in complete wound closure in favour of UrgoStart (p=0.002), as well as a statistically significant increase in absolute wound area reduction (p=0.022). Adverse effects and quality of life were similar in the 2 groups. The external assessment centre (EAC) noted that this was a European international study with some patients recruited from UK centres, but the number of patients recruited per centre was low (median=3) and the study only included patients with neuro-ischaemic ulcers.

Results from CHALLENGE show an increase in wound area reduction in the first 8 weeks for venous leg ulcers

- 3.3 The multicentre, double-blind, international randomised controlled trial

CHALLENGE (n=187; 8-week study period) compared UrgoStart with UrgoTul Absorb, a non-interactive dressing (Meaume et al. 2012 and Meaume et al. 2017). Compression therapy was used in both the intervention and control groups (more than 96% at week 6). The results reported a statistically significant increase in relative wound area reduction (p=0.002) and in absolute wound area reduction (p=0.003) in favour of UrgoStart. Use of UrgoStart also resulted in a statistically significant improvement in the pain and discomfort dimensions of the EQ-5D (p=0.022). Adverse effects and patient acceptance were similar in the 2 groups. The EAC noted that the follow-up period of 8 weeks was potentially too short to assess healing in complex wounds, and only 13 wounds in total were completely healed by the end of the study (equally spread across the 2 treatment arms). No UK sites were included in this study, and there was a small number of patients per centre (mean=4.2).

A pooled analysis of non-observational studies broadly supports the evidence from the randomised controlled trials

- 3.4 Evidence from a pooled analysis of non-comparative data from 8 observational studies (Munter et al. 2017) supported the healing rates of diabetic foot and venous leg ulcers seen with UrgoStart in the randomised controlled trials. The analysis included more than 10,000 patients with chronic wounds, of whom 7,903 had venous leg ulcers and 1,306 had diabetic foot ulcers. However, the EAC noted that there were a range of follow-up periods (4 to 20 weeks), outcome measures and distributions of ulcer type in the included studies.

2023 guidance review

- 3.5 As part of the guidance surveillance process, new clinical evidence for UrgoStart was reviewed. A total of 22 eligible new clinical studies were identified. The EAG did not identify any evidence that contradicts the current NICE guidance for the UrgoStart range. Three studies noted that wound duration at baseline was an important predictor of outcome following UrgoStart use, with a shorter wound duration leading to better wound healing outcomes. There was still not enough evidence to recommend UrgoStart for non-venous leg ulcers because of a lack of

new evidence explicitly in this population. For more on the new evidence, see the [review report](#). [2023]

Cost evidence

The company's models for both leg ulcers and diabetic foot ulcers show cost savings with UrgoStart

3.6 The company presented separate de novo cost-effectiveness models for leg ulcers and diabetic foot ulcers. The leg ulcer model was a Markov model with a 1-week cycle length, which incorporated 3 health states. The diabetic foot ulcer model was more complicated and included 6 health states. The company presented base-case results with a time horizon of 1 year. The results showed that compared with non-interactive dressings, UrgoStart was associated with savings of £274.25 per patient per year for leg ulcers and £666.51 per patient per year for diabetic foot ulcers.

The EAC's changes to the model parameters and its calibrations more accurately reflect NHS costs and consequences

3.7 The EAC considered that both model structures presented by the company adequately captured all the relevant health states, and that the assumptions were valid and reasonable. However, it changed some parameter values with which it did not agree. The EAC also calibrated the models to align with the healing outcomes and resource use from published UK studies (Guest et al. 2018a and 2018b). In its changes to the models, the EAC assumed that:

- diabetic foot ulcers would not heal in 20% of patients and treatment would continue for 1.4 months (6.09 weeks) on average before the dressing was changed to a different product
- leg ulcers would not heal in 37.6% of patients and treatment would continue for 1.9 months (8.26 weeks) on average before the dressing was changed to a different product.

The EAC's updated models show that UrgoStart is likely to be cost saving

- 3.8 Results from the EAC's base-case analysis showed that UrgoStart compared with standard care was associated with cost savings of £541 per patient per year for leg ulcers and £342 per patient per year for diabetic foot ulcers. The main drivers of the savings were the cost of dressings, the transition parameters for healing and infection or complications, and the cost of community nursing and hospital visits. Sensitivity analyses showed that UrgoStart was always cost saving for leg ulcers, but that it became cost incurring for diabetic foot ulcers if the healing rate was assumed to be half of that reported in the EXPLORER trial. For full details of the cost evidence, see [section 4 of the assessment report](#).

4 Committee discussion

Clinical-effectiveness overview

Results from the EXPLORER trial show faster complete healing with UrgoStart dressings in diabetic foot ulcers

4.1 The committee concluded that the EXPLORER study provided convincing evidence that UrgoStart dressings improve complete wound healing in patients with diabetic foot ulcers. It noted the external assessment centre (EAC) conclusions that there was a low risk of bias in this study, and that the reported benefits associated with UrgoStart were also supported by the pooled analysis of non-comparative observational data. Although most of the evidence came from patients with neuro-ischaemic ulcers, a clinical expert advised that similar care is used for both neuropathic and neuro-ischaemic diabetic foot ulcers. The committee concluded that the use of UrgoStart, when used as part of overall management, improves wound healing in people with diabetic foot ulcers.

Results from the CHALLENGE study show a faster rate of early healing with UrgoStart dressings in venous leg ulcers

4.2 The committee concluded that the results of the CHALLENGE study showed an increase in the rate of early wound healing with UrgoStart in patients with venous leg ulcers compared with standard treatment. It noted, however, that the study period of 8 weeks was relatively short, and that the observed treatment benefit was based on measuring increased wound area reduction rather than complete wound closure. The clinical experts confirmed that rapid wound area reduction in the first 8 weeks is a good surrogate for ultimately complete wound closure, but that this is not definitive. The experts stated that venous leg ulcers typically heal completely within 18 to 24 weeks. The committee noted the EAC conclusion that there was a low risk of bias in this study, and also that the benefits associated with UrgoStart were supported by the

observational data. It concluded that UrgoStart improves wound healing in venous leg ulcers when used as part of overall management including compression therapy, although it was uncertain if this would be translated into complete wound closure.

UrgoStart may lead to benefits that are important in improving day-to-day living in people with diabetic foot or venous leg ulcers

4.3 The committee recognised how severely diabetic foot and venous leg ulcers affect people's quality of life. However, it concluded that there was limited published evidence to support any quality-of-life benefits directly as a result of using UrgoStart. The clinical experts explained that increases in wound closure and in the rate of wound area reduction are likely to be associated with improvements in day-to-day living. For people with diabetic foot ulcers, complete wound closure is usually necessary for them to return to unhindered walking. For people with venous leg ulcers, a reduction in the wound area may translate into important benefits including earlier transition to less cumbersome dressings and treatment in the community. The experts' comments were corroborated by a small sample of people who have used UrgoStart dressings and reported quality-of-life benefits associated with improved wound healing. The committee concluded that it was plausible that UrgoStart leads to benefits that are important in improving day-to-day living in people with diabetic foot or venous leg ulcers.

Relevance to the NHS

The evidence for UrgoStart is broadly generalisable to the NHS

4.4 Only a small proportion of the patients with diabetic foot ulcers in the EXPLORER study were recruited from a UK centre. There were no patients from the UK in any of the studies that investigated the benefits of UrgoStart in patients with leg ulcers. Clinical experts stated that the demographics of patients and the fundamentals of wound care are likely to be similar across Europe. However, the experts also explained that some differences in care may exist including, for example, the type of health professional giving the treatment and the compression pressure

used to treat venous leg ulcers. The committee concluded that the evidence for UrgoStart was broadly generalisable to the NHS.

There is insufficient evidence to recommend UrgoStart for non-venous leg ulcers

- 4.5 The committee noted that most of the evidence of UrgoStart providing benefit in patients with leg ulcers was specifically for venous leg ulcers. The clinical experts confirmed that about 70% of leg ulcers are caused by venous disease. They also stated that compression is an important part of standard care for venous leg ulcers, but that treatment of non-venous leg ulcers relies on dressings alone. The committee concluded that even though it is plausible that there are benefits from using UrgoStart for non-venous leg ulcers, there was insufficient evidence to make a definitive recommendation about the use of UrgoStart in this group.

NHS considerations

UrgoStart can be incorporated in care pathways by including it on local formularies

- 4.6 The clinical experts explained that diabetic foot care, including ulcer management, varies across the NHS. Diabetic foot care usually involves a multi-disciplinary team; patients move between GP practice, secondary care and community care depending on their needs. Venous leg ulcers, on the other hand, are mostly treated in a community setting. New and novel dressings are usually incorporated into local care pathways through their inclusion in dressing formularies. The committee did not consider that the use of UrgoStart should be restricted to any particular setting in the NHS, but understood that the decision to use it would usually be made by a multi-disciplinary team or a tissue viability specialist.

UrgoStart should be considered for patients with non-infected ulcers

- 4.7 The clinical experts confirmed that UrgoStart would only be used after a thorough wound and patient assessment, and after interventions to control other modifiable factors including debridement and treatment of wound infection. The experts also agreed that if using UrgoStart dressings did not lead to progress in wound healing, they would change to a different product. The committee concluded that UrgoStart should be recommended for patients with non-infected diabetic foot ulcers or venous leg ulcers.

Cost-modelling overview

The EAC's updated models are more plausible than the company's models and most appropriate for decision making

- 4.8 The committee expressed concerns about the variability seen in wound healing rates, and questioned whether this was correctly reflected in the models. The EAC explained that it had calibrated the models to better reflect this, recognising that not all wounds will improve with treatment and in these instances UrgoStart would be replaced by a different dressing (6.09 weeks for diabetic foot ulcers and 8.26 weeks for venous leg ulcers). The calibration process included using data from the Guest et al. (2018a) and Guest et al. (2018b) papers, which summarised resource-use data taken from an electronic database of patients in 562 GP practices across the UK. These data were used to estimate the proportion of patients whose ulcers had not healed after 1 year in the comparator arms of both analyses. The committee agreed that the EAC's updated models were most appropriate for decision making.

Main cost drivers

Estimates of cost savings are likely to be robust for treating diabetic foot ulcers but are less certain for treating venous leg

ulcers

- 4.9 The committee noted the importance of healing-rate parameters in the cost modelling. It was confident that UrgoStart improved complete wound healing, but was uncertain about the reliability of using an extrapolation method to derive complete wound healing rates from partial healing at 8 weeks in people with venous leg ulcers. In view of this, the committee concluded that the estimates of cost savings are likely to be robust when UrgoStart is used to treat diabetic foot ulcers, but that uncertainty remains about the cost savings when UrgoStart is used to treat venous leg ulcers.

Cost savings

UrgoStart is likely to be cost saving compared with standard care but there are uncertainties in the size of these savings in people with venous leg ulcers

- 4.10 The EAC's did deterministic sensitivity analyses that varied parameters in both cost models. Results showed that the technology remained cost saving in most cases. The committee concluded that, based on the published evidence, cost modelling and expert opinion, UrgoStart is likely to be cost saving compared with non-interactive dressings. For diabetic foot ulcers, the committee agreed with the estimate from the EAC's updated model of a £342 saving per patient per year with UrgoStart. For venous leg ulcers, it accepted that use of UrgoStart is likely to be cost saving but considered any estimates to be less certain, because of the uncertainty in the evidence for complete wound healing.

5 Committee members and NICE project team

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 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 technologies advisory committee 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 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.

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Update information

April 2023: We updated section 1 to reflect the current format of NICE guidance. We also added some text to the [clinical evidence section](#) to summarise new clinical evidence reviewed. NICE's recommendations for UrgoStart remain unchanged. More details are in the [review decision](#). New text is marked **[2023]**.

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