NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG42: UrgoStart for treating diabetic foot ulcers and leg ulcers

This guidance was issued in January 2019.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, or to update to current formats. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Recommendation

Amend the guidance to reflect current format of section 1 (recommendations) and an addition to the clinical evidence section (section 3) to summarise the new clinical evidence reviewed. These changes proposed have no material effect on the recommendations.

Please see Appendix 1 for a list of the options and their explanations for consideration.

2. Original objective of guidance

To assess the case for adoption of UrgoStart for treating diabetic foot ulcers and leg ulcers.

3. Current guidance

1.1. Evidence supports the case for adopting UrgoStart dressings to treat diabetic foot ulcers and venous leg ulcers in the NHS, because they are associated with increased wound healing compared with non-interactive dressings.

1.2. UrgoStart dressings 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.

1.3. Cost modelling shows that, compared with standard care, using UrgoStart dressings to treat diabetic foot ulcers is associated with a cost saving of £342 per patient after 1 year. It also shows that UrgoStart is likely to be cost saving for treating venous leg ulcers, but the robustness of this conclusion is less certain from the evidence available. For both types of ulcers, potential cost savings mainly come from better healing with UrgoStart dressings. If 25% of people having treatment for diabetic foot ulcers use UrgoStart instead of a non-interactive dressing, the NHS may save up to £5.4 million each year. For more details, see the NICE resource impact report.

1.4. For people with non-venous leg ulcers, there is insufficient evidence to support routine adoption.

Why the committee made these recommendations

UrgoStart is a type of interactive wound dressing. Clinical trial evidence shows that using UrgoStart to treat diabetic foot ulcers increases wound healing compared with non-interactive dressings. For venous leg ulcers, the evidence shows that UrgoStart increases the rate of wound healing in the short term compared with non-interactive dressings when used with standard care, but the impact on complete wound healing is less certain. There is much less evidence for non-venous leg ulcers so, although clinical and patient benefits are plausible, there is no positive recommendation about UrgoStart in this patient group. Cost analyses suggest that using UrgoStart as part of the overall management of diabetic foot ulcers and venous leg ulcers could save costs for the NHS.

4. Rationale

Although new studies have been published, all new evidence is in agreement with the evidence reviewed at the time of the original guidance, with the original evidence being of higher methodological quality than more recent publications. The new evidence remained insufficient to make recommendations on the use of the UrgoStart range for non-venous leg ulcers. As a result, it was deemed that no update to the clinical evidence is needed for this guidance.

5. New evidence

The search strategy from the original assessment report was re-run and references from March 2018 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the ‘Summary of

evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The technology is still available in the NHS. There are still 5 formats of the dressing and each still comes in different sizes. There have been no materially significant changes to the costs of the technologies. The range of prices have increased slightly since the original submission, but less than 1% in line with annual Drug Tariff rules on inflationary increases. The range of costs of all formats used to be from £3.03 to £10.20 and now the technologies cost between £3.11 and £10.47.

5.2 Clinical practice

Current care for diabetic foot ulcers (DFUs) as outlined in NICE's guideline on diabetic foot problems: prevention and management had new recommendations on antimicrobial prescribing on diabetic foot infection. However, no changes to recommendations on wound dressing were made. No changes have been made to NICE's guideline on pressure ulcers: prevention and management.

Three clinical experts responded to NICE's request for information. All experts have used or prescribed the UrgoStart range. One expert uses it in care homes, GP practices, and wound care clinics for all complex leg ulcers, with the podiatry team using it for DFUs. Another expert states that UrgoStart use is started in specialist clinics for DFUs and venous leg ulcers (for ulcers that are not healing despite optimal care and standard dressings) and then recommended for ongoing use in community. A third expert agreed the UrgoStart use is split between specialist secondary care clinics and community use for venous leg ulcers and DFUs. In addition to this, 2 of the experts stated that UrgoStart is also used occasionally on other wounds not healing despite optimal care, such as pressure ulcers and surgical wounds. No concerns were raised regarding the use of UrgoStart.

5.3 NICE facilitated research

None.

5.4 New studies

The updated literature searches identified a total of 1339 studies for review (after citation chasing). The company submitted 72 publications (including 1 unpublished study) in response to NICE's request for clinical evidence published after MTG42. After screening, a total of 22 eligible new clinical studies were identified by the EAG.

The EAG did not identify any evidence that contradicts the current NICE guidance for the UrgoStart range as the new clinical evidence consistently favours the use of

UrgoStart. The new evidence reviewed was of lower methodological quality to that considered in the original guidance, meaning that the guidance recommendations are based on the best quality evidence for the technology available.

For the original guidance there was insufficient evidence to recommend UrgoStart for non-venous leg ulcers. The EAG concluded that this has not changed due to a lack of evidence explicitly in this population. Some studies report evidence on venous leg ulcers and leg ulcers of mixed aetiology (Milne and Jones 2018 and Milne and Nichols 2021). However, no definition of mixed aetiology is provided.

A number of studies noted that wound duration at baseline was an important predictor of outcome following UrgoStart use. Lázaro-Martinez et al. (2019), a post hoc analysis of the EXPLORER RCT considered in the original guidance, found that wound closure by week 20 was observed in 71% of those with a diabetic foot ulcer lasting less than or equal to 2 months at baseline (prior to UrgoStart use). For longer diabetic foot ulcer durations, there was 59% wound closure of those lasting 3 to 5 months, 29% of those lasting 6 to 11 months and 22% of those lasting more than 11 months. Two single-arm studies also noted this. Augustin et al. (2021) found that wound healing rates were 59.9% for wounds that occurred in the previous month versus 36.8% in wounds that had already lasted for more than a month, across different wound aetiologies. In Dissemond et al. (2020, healing occurred in 58.3% of wounds occurring in the previous month versus 33.3% of wounds with more than 1 month duration, across wound aetiologies. However, this factor was not considered in the original guidance and diabetic foot ulcer guidelines (NG19) generally recommends taking into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances. Clinical experts state that UrgoStart is used after standard dressings and wound management fail to improve wound healing. This would usually be after 4 to 6 weeks of treatment. The usual timeframe for UrgoStart usage is therefore reasonably in line with the shorter wound duration subgroups where better efficacy of the dressing has been observed. As a result, the new evidence is unlikely to have an impact on this guidance.

The EAG's searches identified 6 relevant new economic studies (three conference abstracts [Betts et al. 2018a; Betts et al. 2018b; Mlcoch et al. 2019] and four peer-reviewed manuscripts [Lobmann et al. 2019; Lobmann et al. 2020; Maunoury et al. 2021]). Most of the economic studies used outcome data from either the EXPLORER (Lobmann et al. 2019; Lobmann et al. 2020; Maunoury et al. 2021; Mlcoch et al. 2019) or CHALLENGE (Betts et al. 2018a; Mlcoch et al. 2019) RCTs which were considered in the original guidance. In all included studies, UrgoStart was a dominant strategy (cost-saving and, where outcomes were also evaluated, at least as effective as comparator), which is in line with the original guidance.

5.5 Cost update

No cost update was done for this technology.

6. Summary of new information and implications for review

The new clinical evidence is unlikely to have a material effect on the recommendations in the published guidance. The EAG did not identify any evidence that contradicts the current NICE guidance. As there is no new robust evidence on the use of the UrgoStart range in people with non-venous leg ulcers, there is still uncertainty in the use of UrgoStart in this population.

7. Implementation

Primary care prescribing data on use of the UrgoStart range exists. This is only a partial representation of UrgoStart prescribing as most people with leg ulcers are treated in the community setting, but most people with diabetic foot ulcers are treated in secondary care services. The prescribed quantities of UrgoStart in primary care are 21,535 for 2019, 21,600 for 2020 and 24,355 for 2021 (NHS Business Services Authority, 2022). The vast majority of prescriptions have been by general practitioners or nurses.

The company provided a list of the top 175 UrgoStart users, which involves clinical commissioning groups, NHS trusts and hospitals.

8. Equality issues

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

No equality issues were raised during the original guidance process although there were some equality considerations listed. This dressing is used to treat people with leg ulcers or diabetic foot ulcers. Women are 2 times more likely to have a leg ulcer than men. 1 in 10 people with diabetic foot ulcers will have an amputation. Diabetic foot and venous leg ulcers affect people's quality of life with experts stating 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. Sex and disability are all protected characteristics under the 2010 Equality Act.

No new equality issues were identified.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	N/A
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	N/A
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	N/A

Appendix 2 – supporting information

Relevant Institute work

Published

- Diabetic foot problems: prevention and management (2015, updated 2019) NICE guideline NG19
- Pressure ulcers: prevention and management (2014) NICE guideline CG179

Registered and unpublished trials

None

Appendix 3 – changes to guidance

Table 1: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
1.1	1.1 Evidence supports the case for adopting UrgoStart dressings to treat diabetic foot ulcers and venous leg ulcers in the NHS, because they are associated with increased wound healing compared with non-interactive dressings. 1.2 UrgoStart dressings 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. 1.3 Cost modelling shows that, compared with standard care, using UrgoStart dressings to treat diabetic foot ulcers is associated with a cost saving of £342 per patient after 1 year. It also shows that UrgoStart is likely to be cost saving for treating venous leg ulcers, but the robustness of this conclusion is less certain from the evidence available. For both types of ulcers, potential cost savings mainly come from better healing with UrgoStart dressings. If 25% of people having treatment for diabetic foot ulcers use UrgoStart instead of a non-interactive dressing, the NHS may save up to £5.4 million each year. For more details, see the NICE resource impact report. 1.4 For people with non-venous leg ulcers, there is insufficient evidence to support routine adoption.	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 type of interactive wound dressing. Clinical trial evidence shows that using UrgoStart to treat diabetic foot ulcers increases wound healing	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

	compared with non-interactive dressings. For venous leg ulcers, the evidence shows that UrgoStart increases the rate of wound healing in the short term compared with non-interactive dressings when used with standard care, but the impact on complete wound healing is less certain. There is much less evidence for non-venous leg ulcers so, although clinical and patient benefits are plausible, there is no positive recommendation about UrgoStart in this patient group. Cost analyses suggest that using UrgoStart as part of the overall management of diabetic foot ulcers and venous leg ulcers could save costs for the NHS.	modelling showed that UrgoStart is cost saving compared to 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 plausible, further evidence is needed to make a recommendation.
3.8		**2023 guidance review** 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 due to a lack of new evidence explicitly in this population. For more on the new evidence see the evidence review report. [2023]

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