Wounds UK

NICE recommendations for UrgoStart™ treatment range

made easy

June 2019

Introduction

This Made Easy describes the rigours of NICE guidance development, and the importance of applying evidence in practice. It focuses on the recently published Medical Technologies Guidance that supports the use of UrgoStart™ treatment range (Urgo Medical) to treat diabetic foot ulcers and venous leg ulcers.

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WHAT IS THE IMPACT OF WOUNDS TODAY?

Chronic wounds make up 39% of all wounds and cost over twice as much as acute wounds to treat (Guest et al, 2017a). The prevalence of wounds is rising at a rate of 9–13% per year (Guest et al, 2017b) as a result of population ageing and the increasing incidence of comorbid conditions, such as diabetes and vascular disease, which can have a negative impact on healing. The NHS spends £5.3 billion each year treating wounds and their associated comorbidities (Guest et al, 2015).

Clinical practice should focus on wound prevention, accurate diagnosis and healing strategies to improve outcomes (Guest et al, 2015). For this, practice needs to be informed by robust clinical evidence; something several Cochrane reviews concluded has been lacking for wound care products (Dumville et al, 2015a; 2015b; Wu et al, 2015).

The overuse of ineffective interventions and underuse of evidence-based treatments continues to occur in practice (Gray et al, 2018). Busy clinicians cannot read every paper published or may not be skilled in methodology appraisal, so evidence-based guidance is important to inform our practice and improve the quality and consistency of the care we provide.

NICE AND WOUND CARE DELIVERY

What is the role of NICE?

The National Institute for Health and Care Excellence (NICE) is an independent organisation that produce evidence-based recommendations (e.g. NICE guidelines, technology appraisal guidance, medical technology) on a wide range of topics, which aim to improve healthcare provision and standardise care.

What is NICE Medical Technologies Guidance?

Medical Technologies Guidance (MTG) is a type of NICE guidance and evaluates new, innovative medical devices, such as advanced wound dressings, to determine whether they should be adopted in practice and whether they provide value for money to health services (Box 1).

Box 1. NICE criteria for medical technologies guidance assessment.

- ✔ New or innovative technology that has, or expected to receive, regulatory approval within a year.
- ✔ Evidence of substantial benefits for patients and/or the NHS in comparison with current practice.
- ✔ Supported by clinical evidence.
- ✔ Likely to be adopted more quickly and consistently into practice if NICE develops guidance on them.

DELIVERING THE BEST CARE: A NATIONAL STRATEGY

The National Wound Care Strategy (NWCS) Programme represents a long-term commitment to improving patient care. The NWSC aims to promote collaboration and improvement in wound management (Box 2; Adderley, 2018). Its three clinical workstreams – pressure ulcers, surgical wounds and lower limb wounds – are supported by enabler workstreams that will support the adoption and spread of the outputs. Both the NWCS Programme and NICE are committed to ensuring patients receive high-quality wound care services that apply evidence-based, cost-effective treatment to reduce time to healing and improve healing rates and quality of life.

Box 2. Aims of the National Wound Care Strategy Programme (Adderley, 2018).

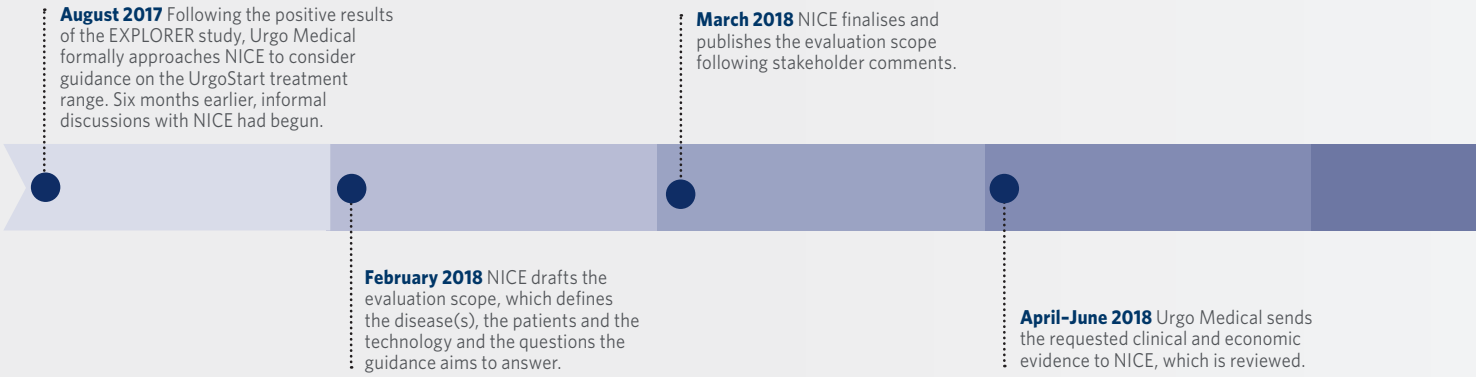
- To develop evidence-based care pathways.
- To improve the supply and distribution of wound care products.
- To create national information sets to measure performance.
- To provide appropriate education for everyone involved in wound care.

URGOSTART™ RECOMMENDED BY NICE FOR TREATING DIABETIC FOOT ULCERS AND VENOUS LEG ULCERS

Based on available clinical and economic evidence, UrgoStart treatment range is the first wound care product to be recommended for treatment of diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) (NICE, 2019a). This is a real breakthrough for wound care technology.

NICE recommendations for UrgoStart™ treatment range made easy

Figure 1. Timeline to NICE Medical Technologies Guidance 42 for UrgoStart treatment range. EAC=External assessment centre; MTAC= Medical Technologies Advisory Committee.



NICE Medical Technologies Guidance 42

Following 2 years of evidence submission and consultation of the clinical and cost effectiveness (Figure 1), NICE (2019a) published evidence-based recommendations that support the adoption of the UrgoStart treatment range to treat DFUs and VLUs:

> *"[UrgoStart dressings] are associated with increased wound healing compared with non-interactive dressings. 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."*

A clinically effective treatment

NICE reviewed clinical evidence that supported the use of UrgoStart treatment range (Figure 2) and demonstrated significant efficacy in reducing healing time:

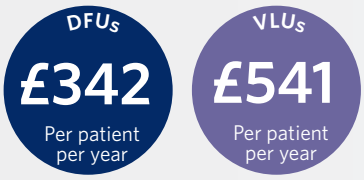
- The **EXPLORER** multicentre, European, double-blind randomised controlled trial compared UrgoStart with a non-interactive dressing in DFU treatment over 20 weeks. It reported a statistically significant increase in complete wound closure and a statistically significant decrease in wound area in favour of UrgoStart (Edmonds et al, 2018). The Medical Technologies Advisory Committee (MTAC) concluded the trial provided convincing evidence that UrgoStart improves complete DFU healing, had a low risk of bias, and that the reported benefits were supported by the **REALITY** pooled analysis of 7,903 patients with VLUs and 1,306 patients with DFUs followed up for 4–20 weeks (Münter et al, 2017).
- **CHALLENGE** was a double-blind randomised controlled trial comparing the use of UrgoStart with a non-interactive dressing in the treatment of VLUs (Meaume et al, 2012; 2017). During the 8-week follow-up period, there were significantly greater reductions in relative and absolute wound area with UrgoStart compared to the non-interactive dressing. UrgoStart also had a positive impact on patients' health-related quality of life, with significant improvements in the pain/discomfort and anxiety/depression domains of the EuroQoL 5D questionnaire (Meaume et al, 2012; 2017). The MTAC agreed that **CHALLENGE** demonstrated an increased rate of early VLU healing and agreed with the external assessment centre (EAC) that the follow-up period may have been too short to assess the impact of UrgoStart on complex wound healing, as VLUs typically take 18–24 weeks to heal completely.

Having reviewed the clinical evidence, NICE stated that UrgoStart treatment range should be considered for patients with non-infected DFUs and VLUs. Additional expert and patient comments on the impact of DFUs and VLUs on quality of life, and the positive impact of wound closure, led the MTAC to conclude that UrgoStart use may result in benefits important to improvements in patients' day-to-day living.

It proposed UrgoStart treatment range be incorporated into care pathways through inclusion in local formularies, and does not need to be restricted to any particular setting in the NHS.

A cost-effective treatment

In addition to clinical evidence, economic evidence was reviewed and cost-effectiveness models were presented for DFUs and VLUs. The base-case analysis showed that UrgoStart treatment range was associated with cost saving of:



NICE concluded that if a quarter of people with DFUs were treated with UrgoStart treatment range in addition to the standard care, the NHS could save £5.4 million annually.

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September 2018 An independent EAC reviews and critiques the evidence (Figure 2). The EAC evaluates medical technologies, and prepares an assessment report overview highlighting the key issues in the submission from Urgo Medical. The MTAC have monthly meetings, which are open to the public, and develop draft recommendations considering all the evidence presented. A consultation document with draft recommendations is prepared.

October 2018 Draft recommendations are published online and consultation is open for 4 weeks.

November 2018 The MTAC meets and considers consultation comments and develops final recommendations.

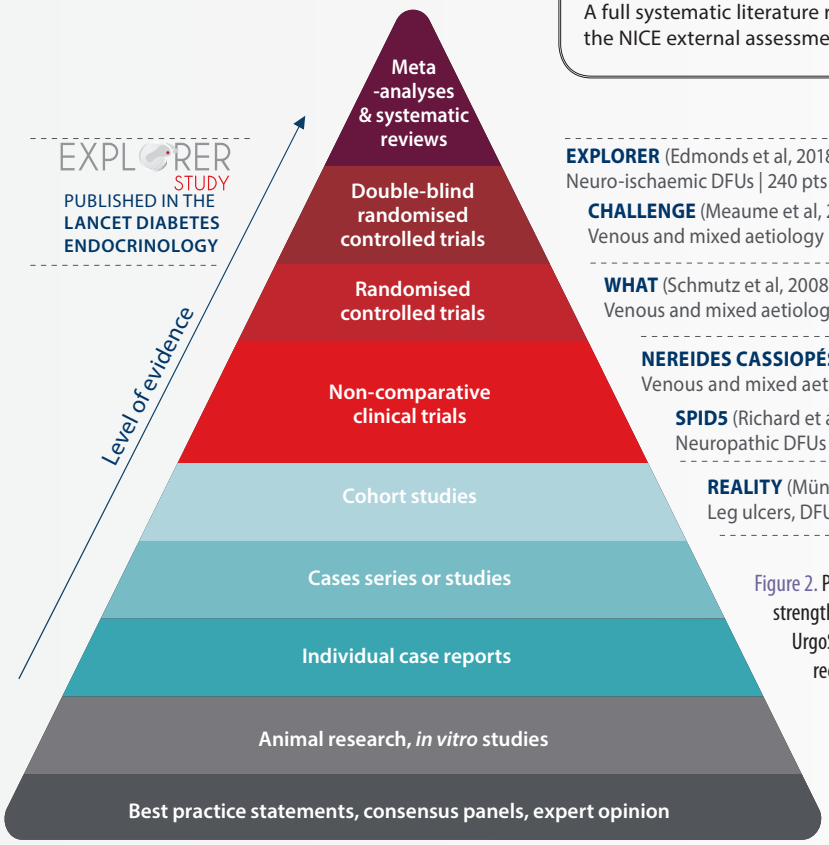
December 2018–January 2019 The recommendations are open to resolution for 3 weeks — a final quality assurance step before the guidance is published. Corrections can be requested if there has been a breach of process or there are factual errors in the guidance.

January 2019 NICE publishes Medical Technologies Guidance 42.

NICE recommends the adoption of UrgoStart treatment range for DFUs and VLUs in practice by:

- Including it in appropriate DFU and VLU care pathways
- Offering appropriate staff education and training
- Including it on local formularies
- Having a dedicated implementation team to help with its adoption.

A full systematic literature review was submitted and accepted as fair by the NICE external assessment centre.



EXPLORER (Edmonds et al, 2018): double-blind RCT (vs neutral dressing)
Neuro-ischaemic DFUs | 240 pts

CHALLENGE (Meaume et al, 2012): double-blind RCT (vs neutral dressing)
Venous and mixed aetiology leg ulcers | 187 pts

WHAT (Schmutz et al, 2008): RCT (vs competitor)
Venous and mixed aetiology leg ulcers | 117 pts

NEREIDES CASSIOPÉS (Sigal et al, 2019): clinical study
Venous and mixed aetiology leg ulcers | 41 pts

SPID5 (Richard et al, 2012): clinical study
Neuropathic DFUs | 34 pts

REALITY (Münter et al, 2017): pooled data analysis
Leg ulcers, DFUs, pressure ulcers | 10,220 pts

Figure 2. Pyramid of evidence emphasises the strength of evidence to support the use of UrgoStart in a range of wound aetiologies. NICE recommendations for the use of UrgoStart treatment range for DFUs and VLUs were based on clinical and economic evidence from pooled data analysis, clinical studies, RCTs and double-blind RCTs.

TOOLS TO ADOPT GUIDANCE

NICE provides practitioners with online support to implement guidance with practical steps to making changes in practice (Figure 3). For MTG42, NICE's adoption team worked with contributors of the guidance who use UrgoStart treatment range to gather learnings and experiences that would support clinicians to adopt into local care pathways. Advice on education and training for the UrgoStart treatment range to increase clinical confidence and ensure appropriate patient selection is available. There is also a tool to help demonstrate potential cost savings of adopting UrgoStart treatment range. These can be accessed here: www.nice.org.uk/guidance/mtg42/resources.

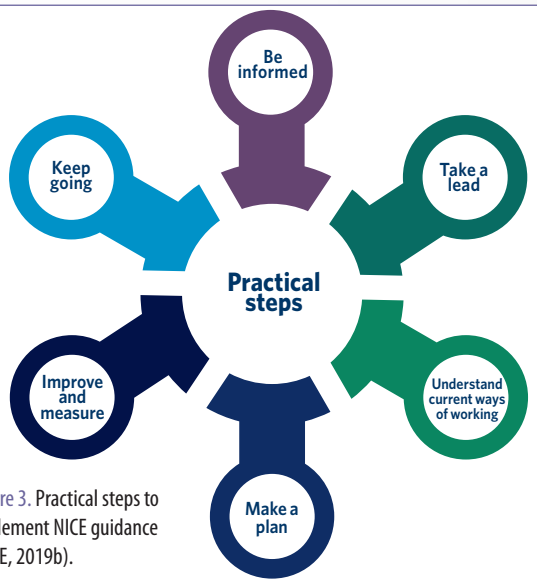


Figure 3. Practical steps to implement NICE guidance (NICE, 2019b).

What is the UrgoStart™ treatment range?

UrgoStart is an interactive dressing and should be used in conjunction with standard care for DFUs and VLUs (including offloading and compression therapy, etc.). UrgoStart heals wounds twice as fast as a neutral absorbent dressing, preventing chronicity and improving patient quality of life (Meaume et al, 2012). It has also been shown that the sooner UrgoStart treatment is initiated, the shorter the healing time (Manu et al, 2019). UrgoStart is indicated for diabetic foot ulcers, leg ulcers, pressure ulcers and long-standing acute wounds.

How does the UrgoStart treatment range work?

UrgoStart treatment range contains Technology Lipido-Colloid-Nano-Oligo Saccharide Factor (TLC-NOSF) impregnated in an open-weave polyester mesh (TLC-NOSF Healing Matrix). TLC-NOSF has two unique modes of action:

- It is a protease inhibitor that prevents the continued degradation of extra-cellular matrix by excess matrix metalloproteinases (MMPs) (White et al, 2015; Lazaro et al, 2016).
- It promotes angiogenesis through migration and proliferation of endothelial cells (White et al, 2015, Edmonds et al, 2018).

On contact with exudate, TLC-NOSF Healing Matrix forms a lipido-colloid gel to create and maintain a moist environment. The actions of TLC-NOSF restore balance within the wound bed, allowing granulation and progression to healing.

TLC-NOSF is available in five different formats: **UrgoStart Contact, UrgoStart Plus Pad*, UrgoStart Plus Border***, **UrgoStart**, **UrgoStart Border**.

*The UrgoStart Plus range has the added advantage of poly-absorbent fibres, which clean the wound and keep it clean throughout healing.

REFERENCES

Adderley U (2018) Our vision for the National Wound Care Strategy Programme. *Wounds UK* 14(5):31

Dumville JC, Keogh SJ, Liu Z et al (2015a) Alginate dressings for treating pressure ulcers. *Cochrane Database Syst Rev* (5): CD011277

Dumville JC, Stubbs N Keogh SJ et al (2015b) Hydrogel dressings for treating pressure ulcers (review). *Cochrane Database Syst Rev* (2):D011226

Edmonds M, Lazaro-Martinez JL, Alfayate-Garcia JM et al (2018) Sucrose octasulfate dressing versus control dressing in patients with neuroischaemic diabetic foot ulcers (Explorer): an international, multicentre, double-blind, randomised, controlled trial. *Lancet Diabetes Endocrinol* 6: 186–96

Gray TA, Rhodes S, Atkinson RA et al (2018) Opportunities for better value wound care: a multiservice, cross-sectional survey of complex wounds and their care in a UK community population. *BMJ Open* 8:e019440

Guest JF, Ayoub N, McIlwraith T et al (2015) Health Economic burden that wounds impose on the National Health Service in the UK. *BMJ Open* 5:e009283

Guest JF, Ayoub N, McIlwraith et al (2017a) Health economic burden that different wound types impose on the UK's National Health Service. *Int Wound J* 14(2):322-330

Guest JF, Vowden K, Vowden P (2017b) The health economic burden that acute and chronic wounds impose on an average clinical commissioning group/health board in the UK. *J Wound Care* 26(6):292–303

Lazaro JL, Izzo V, Meaume S et al (2016) Elevated levels of matrix metalloproteinases and chronic wound healing: an updated review of clinical evidence. *J Wound Care* 25(5): 277–87

Manu C, Edmonds M, Lázaro-Martínez JL et al (2019) Efficacy of sucrose-octasulfate dressing in neuro-ischaemic DFU considering factors influencing wound closure rate; a post-hoc analysis of the Explorer RCT. Oral communication presented at: *International Symposium of the Diabetic Foot*. The Hague, The Netherlands, 22-25 May

Meaume S, Truchetet F Cambazard F et al (2012) A randomized, controlled, double-blind prospective trial with a Lipido-Colloid Technology-Nano-OligoSaccharaide Factor wound dressing in the local management of venous leg ulcers. *Wound Repair Regen* 20: 500–11

Meaume S, Dompmartin A, Lok C et al (2017) Quality of life in patients with leg ulcers: results from CHALLENGE, a double-blind randomised trial. *J Wound Care* 26(7): 368–79

Münter KC, Meaume S, Augustin M et al (2017) The reality of routine practice: a pooled data analysis on chronic wounds treated with TLC-NOSF wound dressings. *J Wound Care* 26(Suppl 2): S4–S15

NICE (2019a) *Medical technologies guidance 42: UrgoStart for treating diabetic foot ulcers and leg ulcers*. NICE: London. Available at: www.nice.org.uk/guidance/mtg42 (accessed 17.04.19)

NICE (2019b) *Practical steps to improving the quality of care and services using NICE guidance*. NICE: London. Available at: https://bit.ly/2WbQtLn (accessed 17.04.19)

Richard JL, Martini J, Bonello Faraill MM et al (2012) Management of diabetic foot ulcers with a TLC-NOSF wound dressing. *J Wound Care* 21(3):142-7

Schmutz J-L, Meaume S, Fays S et al (2008) Evaluation of the nano-oligosaccharide factor lipido-colloid matrix in the local management of venous leg ulcers: results of a randomised, controlled trial. *Int Wound J* 5: 172–82

Sigal ML, Addala A, Maillard H et al (2019) Evaluation of TLC-NOSF dressing with poly-absorbent fibres in exuding leg ulcers: two multicentric, single-arm, prospective, open-label clinical trials. *J Wound Care* 28(3): 164–75

White R, Cowan T, Glover D (2015) *Supporting evidence-based practice: a clinical review of TLC healing matrix* (2nd edition). London: MA Healthcare Ltd

Wu L, Norman G, Dumville JC et al (2015) Dressings for treating foot ulcers in people with diabetes: an overview of systemic reviews. *Cochrane Database Syst Rev* (7):CD010471