

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology guidance

### SCOPE

## UrgoStart for the treatment of leg ulcers and diabetic foot ulcers

### 1 Technology

#### 1.1 *Description of the technology*

UrgoStart (Urgo Medical) is a dressing used to treat chronic wounds. The indications to be addressed in this evaluation are leg ulcers and diabetic foot ulcers. There are 5 different formats of the dressing: UrgoStart Contact Layer, UrgoStart Non-Adhesive, UrgoStart Plus Pad, UrgoStart Border and UrgoStart Plus Border.

The UrgoStart dressings contain a layer of open weave polyester mesh, impregnated with hydrocolloid polymers, within a petroleum jelly. This is called technology lipido-colloid (TLC) and it is intended to create a moist, protective, wound healing environment. The innovative element of UrgoStart is that it contains nano-oligosaccharide factor (NOSF) which inhibits protease activity, specifically matrix metalloproteinases. There is evidence that high levels of proteases (enzymes) in wounds are linked to slower wound healing.

UrgoStart dressings are intended for use by a healthcare professional and may be used in a community or hospital setting. The instructions for use state that UrgoStart should be applied for a minimum of 8 weeks unless the wound heals during that time, with dressing changes every 2 to 4 days, with a maximum interval of 7 days. Treatment of any area of infection is recommended before using the dressing.

## **1.2 Regulatory status**

All UrgoStart products are CE marked as class IIb devices. The CE marks for the different UrgoStart dressings were awarded between 2006 and 2016.

## **1.3 Claimed benefits**

The company claims that the benefits to patients compared with standard care are:

- Reduced wound healing time
- Higher wound healing rate
- Increased wound area reduction
- Increased wound closure rate
- Lower risk of complications including amputation
- Improved quality of life.

The company claims that the benefits to the healthcare system compared with standard care are:

- Reduced cost because of fewer nurse, GP and outpatient visits
- Reduced total number of dressings needed
- As wounds heal faster, there may be fewer wound-related complications that need additional treatment and healthcare professional resources and cost.

## **1.4 Relevant diseases and conditions**

Venous leg ulcers are estimated to affect around 1 in 500 people in the UK and they become much more common with age. It is estimated that around 1 in 50 people over the age of 80 are affected.<sup>1</sup> There is no difference in prevalence between socio-economic classes but, in people from lower social classes, they take longer to heal.<sup>2</sup> In patients under 40 years of age, men are more likely to have a venous leg ulcer but overall women are 2 times more

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<sup>1</sup> <https://www.nhs.uk/conditions/leg-ulcer/>

<sup>2</sup> <https://patient.info/doctor/leg-ulcers-pro>

likely to have one than men. <sup>3</sup>In 2001, it was estimated that the cost of treating one venous leg ulcer was between £1,298 and £1,526 per year<sup>4</sup>. About 80% of leg ulcers are managed in the community. <sup>5</sup>

Between 2006 and 2013, the number of people diagnosed with diabetes increased by around 50%, from 1.9 to 2.9 million. [According to Diabetes UK](#), it is estimated that 1 in 20 people with diabetes will develop a foot ulcer each year, and of these, more than 1 in 10 will ultimately require amputation. Foot problems in people with diabetes have a significant financial impact on the NHS and impact on primary and community care, outpatient costs, bed occupancy and prolonged hospital stays. A report published in 2012 by NHS Diabetes estimated that around £650 million (or £1 in every £150 the NHS spends) is spent on managing foot ulcers or undertaking amputations each year. Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation and around 50% dying within 5 years of developing a diabetic foot ulcer.<sup>6</sup>

## **1.5 Current management**

NICE has published a Clinical Knowledge Summary on [venous leg ulcers](#). It recommends that low-adherent dressings are applied and replaced weekly. Alternative dressings to consider are hydrocolloid for pain, alginate for heavy exudate and hydrogels for slough. The Scottish Intercollegiate Guideline Network (SIGN) guideline on the [management of venous leg ulcers](#) recommends simple non-adherent dressings and compression therapy. Most patients with leg ulcers are treated in the community.

NICE has published a guideline on the prevention and [management of foot problems in people with diabetes](#). It states that clinical assessment and patient preference should inform dressing choices but that healthcare professionals should choose the lowest cost dressing that is likely to achieve

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<sup>3</sup> NICE (2016) Clinical Knowledge Summary, Leg ulcer- venous

<sup>4</sup> SIGN (2010) Management of chronic venous leg ulcers: a national guideline

<sup>5</sup> NICE (2016) Clinical Knowledge Summary, Leg ulcer- venous

<sup>6</sup> NICE (2016) NG19, Diabetic foot problems: prevention and management

the desired results. [NICE advice](#) states that there is not enough evidence to determine if advanced dressings (such as hydrocolloids, alginates, film, foam and hydrofibre dressings) are more clinically effective than conventional dressings for treating wounds. [NICE advice](#) also states that there is not currently robust evidence supporting the use of antimicrobial dressings (such as silver, iodine or honey) over non-medicated dressings for treating chronic wounds. Patients with diabetic foot ulcers are treated in community, hospital and primary care settings.

## 2 Statement of the decision problem

	<b>Scope issued by NICE</b>
Population	Patients with leg ulcers in any setting Patients with diabetic foot ulcers in any setting
Intervention	UrgoStart dressing formats which contain the TLC-NOSF technology
Comparator(s)	Other wound dressing including conventional wound dressings and advanced wound dressings. Standard care is likely to vary with the different types of wounds and stage of healing.
Outcomes	The outcome measures to consider include: <ul style="list-style-type: none"> <li>•time to complete wound healing</li> <li>•time to wound closure</li> <li>•wound area reduction (WAR)</li> <li>•wound area progression</li> <li>•wound healing rate</li> <li>•health related quality of life (HRQoL)</li> <li>•patient tolerance</li> <li>•patient acceptability</li> <li>•device-related adverse events</li> <li>•nurse, GP and outpatient visits</li> <li>•amputation rates</li> <li>•wound-related complications</li> <li>•total dressings used</li> </ul>
Cost analysis	Costs will be considered from an NHS and personal social services perspective. Settings to be considered should include primary care, community and hospital. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	<ul style="list-style-type: none"> <li>•Patients with venous leg ulcers</li> <li>•Patients with arterial leg ulcers</li> <li>•Patients with leg ulcers of mixed aetiology</li> <li>•Patients with diabetic foot ulcers</li> <li>•Patients with chronic ulcers</li> <li>•Patients with non-healing ulcers</li> <li>•Pressure ulcers</li> </ul>

Special considerations, including those related to equality	<p>Leg ulcers are more common in older people.</p> <p>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. Leg ulcers, and diabetic foot ulcers may be associated with other disabilities. People with leg ulcers or diabetic foot ulcers may meet the criteria for being disabled under the Equality Act 2010.</p> <p>Age, sex and disability are all protected characteristics under the 2010 Equality Act.</p>	
Special considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No*
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No*
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No*

## Related NICE guidance

### Published

- Diabetic foot problems: prevention and management. NICE clinical guideline 19, (2016). Available from <https://www.nice.org.uk/guidance/ng19>

### Under development

The medical technologies evaluation programme is unaware of any other NICE guidance being developed.

## **3 Professional organisations**

### **3.1 Professional organisations invited to comment on the draft scope**

The following societies have been alerted to the availability of the draft scope for comment:

- European Wound Management Association
- Royal College of Nursing
- Tissue Viability Society
- Vascular Society of Great Britain & Ireland
- Society of Chiropodists and Podiatrists
- Primary Care Diabetes Society

### **3.2 Patient organisations**

NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Age Related Diseases and Health Trust
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Foot in Diabetes UK (FDUK)
- InDependent Diabetes Trust
- Juvenile Diabetes Research Foundation (JDRF)
- Leg Ulcer Charity
- Limbless Association
- Lindsay Leg Club Foundation
- Pressure Ulcers UK
- The Circulation Foundation
- The Relatives and Residents Association
- Vascular Society of Great Britain and Ireland

- Vasculitis UK
- Your Turn