

Late-stage assessment

GID-HTE10048 Compression products for treating venous leg ulcers

Final scope

1 Introduction

The topic has been identified for late-stage assessment (LSA) by NICE. LSA aims to assess technologies that are in widespread or established use in the NHS. Over time, technologies in use often undergo continuous or incremental innovation and adaptation. LSA will assess whether price variations between technologies are justified by the incremental differences and advancements, and which technologies represent value for money. It will support clinical practitioners, managers, and commissioners in using NHS resources as effectively as possible and ensure that patient and system benefits are maximised.

The technologies identified for this assessment are compression products available for use in the NHS. The evaluation will assess the clinical and economic benefits of compression products for treating venous leg ulcers, as well as evaluating how product features impact outcomes and user preference.

1.1 Population

There are an estimated 739,000 leg ulcers in England, with estimated associated healthcare costs of £3.1 billion per year ([National Wound Care Strategy Programme \[NWCSP\], 2020](#)). Leg ulcers are ulcers that originate on or above the ankle but below the knee and take more than 2 weeks to heal. Most leg ulcers happen because of venous insufficiency (60-80%), but other causes include peripheral arterial disease, reduced mobility, or cardiac failure. Venous leg ulcers typically occur between the ankle and mid-calf and is caused by sustained venous hypertension. Chronic venous insufficiency is a

result of a venous valve incompetence or an impaired calf muscle pump ([NICE CKS, 2024](#)).

The mean annual NHS cost per person varied greatly from £2,036 for healed venous leg ulcers compared to £7,886 for unhealed venous leg ulcers ([Guest et al. 2020](#)). A more recent study examined and estimated the direct healthcare costs of treating people with open venous leg ulcers in the UK ([Urwin et al. 2022](#)). It derived a point prevalence for venous leg ulcers of 3.2 per 10,000 population and estimated that the national cost of treating them was £102 million with a per person annual cost of £4,790. The majority of those with a venous leg ulcer were receiving some type of bandage, which included both compression and non-compression bandages (74.6%).

1.2 Current management of venous leg ulcers

The [NWCSP leg ulcer recommendations \(2023\)](#) state that first line treatment for suspected venous leg ulcers with adequate arterial supply is strong compression therapy ([NWCSP](#)). However, anyone with 'red flag' symptoms or conditions such as acute infection, symptoms of sepsis, acute or suspected chronic limb threatening ischaemia, suspected acute deep vein thrombosis, suspected skin cancer or bleeding varicose veins should be immediately escalated to the relevant clinical specialist. For those without 'red flag' symptoms or conditions, mild graduated compression should be offered (20mmHg or less at the ankle), and arrangements should be made to undertake a comprehensive assessment within 14 days of identification. This assessment covers general health, the ulcer, and the leg and aims to identify underlying causes of the ulcer and to inform suitable treatment ([NWCSP](#)). It includes vascular assessment of arterial supply using ankle brachial pressure index (ABPI). During this assessment, causes for non-healing should be identified and a plan should be formulated to address those causes. The [NWCSP](#) recommends that people with suspected venous disease with adequate arterial supply should be referred to vascular services for diagnosis of venous disease (often includes a clinical assessment with venous duplex scan) and possible vascular intervention to treat the venous insufficiency in line with [NICE's varicose veins guideline](#).

The [NWCSP](#) recommendations state strong compression therapy for suspected venous leg ulcers can be delivered by an elastic system applied to give at least 40mmHg of pressure at the ankle, or an inelastic system applied in accordance with manufacturer's recommendations. Strong compression hosiery should be considered as first-line compression therapy choice where possible and the need for application aids should be considered. However, strong multi-component compression bandaging (in preference to compression hosiery) should be offered to those with:

- chronic ankle or leg oedema which is not reduced by elevation, or
- abnormal limb shape, or
- copious exudate, or
- very fragile skin.

[NICE's guideline on shared decision-making](#) highlights that people have the right to make informed decisions about their care and should understand the choices available to them. When choosing compression products, consideration should also be given to sensation. People with impaired sensation may be unable to identify discomfort from inappropriately applied compression therapy. So, they may need closer monitoring. For those with advanced, unstable cardiac failure, the [NWCSP](#) recommends to liaise with their cardiac clinician or heart failure nurse to agree how to offer compression to optimise healing while minimising additional cardiac burden.

Within 24 to 48 hours of initiating compression, the skin should be assessed for potential complications. The leg ulcer should be cleaned and dressed appropriately before compression is applied. The choice of compression dressing used should be made by a trained health care professional such as a tissue viability or district nurse taking into account the person's preferences. The strongest level of compression that people can tolerate should be offered and sometimes people remain on reduced compression. All compression products should be applied in line with the manufacturer's instructions.

People are predominantly managed in the community by trained tissue viability, district or community nurses, practice nurses, GPs and healthcare

assistants. People with a venous leg ulcer typically have one nursing visit or dressing change every 2 to 3 days. However, depending on the condition of the wound this can switch to once a week, if exudate reduces. Alternatively, if there are high levels of oedema, exudate or lymphorrhoea, then dressing changes may take place daily. Over 90% of people with a recorded venous leg ulcer were prescribed compression bandages or compression hosiery (Guest et al. 2020).

During the ongoing care of venous leg ulcers and review of healing, healthcare professionals should review the reduction in ankle circumference and consider whether compression therapy should be adapted. If at 12 weeks the leg ulcers remain unhealed, they should be escalated for advice in line with local care pathways([NWCSP](#)).

2 Technologies

This section describes the purpose and features of compression products for treating venous leg ulcers, as well as the NHS market based on information provided to NICE by companies, commissioning and clinical experts, and information available in the public domain.

2.1 Description of the technologies

Compression products are products that work by squeezing the lower limb, thereby reducing oedema and helping venous blood return to the heart. Compression products can vary in the level of pressure applied. For venous leg ulcers, strong compression is recommended, which is either an elastic, inelastic or a combination compression system, applied in accordance with manufacturers' recommendations, and designed to give at least 40mmHg of pressure at the ankle.

The focus of this evaluation is on primary and community care because this is a key area of compression product use across the NHS. Part IX of the Drug Tariff contains compression products that have been approved by NHS Prescription Services for prescribing at NHS expense by an appropriate practitioner in primary or community care. Therefore, for this assessment,

NICE will consider all compression products, indicated for treating venous leg ulcers, that are currently available for NHS prescription as part IX of the Drug Tariff. Compression products for treating venous leg ulcers are also included in the [NHS Supply Chain framework for Vascular Therapy and Associated Products](#) (the current framework contract ends 27 February 2026 but includes an option to extend for an additional 24 months). The products in the framework are used in theatres, post-surgery and other wards, but also in the community. Therefore, this assessment will consider also those compression products for treating venous leg ulcers available on the NHS Supply Chain framework that are used in the community setting. Compression products can be purchased as kits which include a number of different bandages or the individual bandages can be purchased separately and combined as needed. This assessment will focus on compression kits or systems because these products are expected to capture the relevant features which will be considered in the assessment. Where possible, scenario analyses will be run to explore the impact of the availability of individual bandages as well as kits. The list of technologies included in this evaluation is not exhaustive and other technologies may be available to the NHS currently or in the future. The use of compression products in children will not be included in this assessment.

2.2 Technology features

The 4-layer compression bandage system was developed in 1988 and has been regarded as the gold standard compression system for treating venous leg ulcers ([Moffatt et al. 1988](#)). After this, 2-layer compression hosiery became available as a treatment option following the results from the VenUS 4 trial ([Ashby et al. 2014](#)). In addition, two alternative types of compression treatments are available in the NHS and are being assessed in the VenUS 6 trial: the 2-layer bandage compression system and compression wraps. Currently, the most commonly used compression products in the NHS are 4- and 2-layer compression bandage systems.

4-layer compression bandage systems

Compression bandages can be made of either relatively inextensible, short stretch materials such as cotton, or of highly extensible, elastomeric fibres.

Typically, the 4-layer system starts with a single layer of orthopaedic wool which is applied in a spiral from toe to knee. The second layer is a Type 1 conforming or Type 2 light support bandage (British standards classification) applied in a spiral, which is followed by an elastic long stretch bandage applied by a figure of eight method or a spiral method. The final layer is a cohesive bandage applied in a spiral. Some systems only have 3 bandages (for example if ankle circumference is larger than 25cm). The 4-layer compression bandage systems are commercially available as kits but the layer components may also be purchased separately.

2-layer compression bandage systems

There are 2 types of 2-layer compression bandage systems:

- a 2-layer system where the first bandage layer typically uses a padding layer for comfort and gripping the skin and the second layer consists of a short stretch compression bandage
- a 2-layer multicomponent compression bandage system where both layers are compression bandages.

Both 2-layer compression bandage systems are thinner than the 4-layer system and designed to allow people to have better mobility. They allow for existing footwear to be worn. The 2-layer compression bandage systems are available as kits but the layer components may also be purchased separately.

2-layer compression hosiery

The 2-layer compression hosiery consists of 2 stockings that together are designed to deliver strong compression (40mmHg) at the ankle. Several of these have been designed with an understocking which is a smooth first layer providing light compression (typically 10 to 20mmHg). A second overstocking then slips over the understocking and delivers the remaining compression. The level of compression delivered differs between manufacturers and if the product has been designed to meet British Standard or European Standard.

Compression wraps

Compression wraps are either a system of Velcro straps which fit together, or a hook and eye system, that people can manage themselves. They aim for people to have better mobility. They are currently recommended for people with lower leg oedema or lymphoedema, but clinical experts have advised that they are used for treating venous leg ulcers. Manufacturers noted that the wraps are indicated for venous leg ulcers in their instructions for use. The [VenUS 6 trial](#) is evaluating compression wraps compared to the other compression products described above.

Different multi-layer compression bandage kits are outlined in the British National Formulary (BNF), consisting of slightly different components including number of layers, level of stiffness, presence of pressure indicator and different lengths and ankle sizes. For the 2-layer compression hosiery and wraps, they can come in different materials, knit (flat or circular), colours, sizes, lengths, and with open or closed toe. With appropriate training, education and aids, 2-layer compression hosiery and compression wraps can be used by people to manage their own care. Compression hosiery and wraps are also reusable, whereas the bandages can only be used once. Supporting products for example a hosiery applicator, a 'boot' to protect bandages when showering, a 'shoe' or an oversized sandal to help walking with bandages, or a foot, ankle or toe piece for wraps to provide full leg compression are available to use with compression products. They are commonly used but the use may vary in different settings. In specialised clinics these supporting products may be offered more routinely than in the community settings.

2.3 Current NHS market for the technologies

In community and primary care, compression products are supplied using an NHS prescription for technologies listed in part IX of the Drug Tariff or the NHS Supply Chain framework. There are also alternative off medical prescription procurement platforms for compression products. There are at least 20 companies providing over 200 compression products (including different sizes, products and colours) to the NHS across a range of procurement routes. There is price variation between the different types of

compression products and within types of compression products. Table 1 provides an overall picture of the size of the offering and price variation in part IX of the Drug Tariff (the data is from June 2024 and the numbers may change during this assessment, price variation depends on which products are included in the groupings).

Table 1. Compression products and prices listed in part IX of the Drug Tariff (June 2024)

Compression product type	Number of products	Number of companies	Price range*
4-layer bandage kits	19	4	£5.73 to £11.04
2-layer bandage kits	37	6	£7.26 to £10.93
2-layer hosiery	18	10	£15.67 to £35.32**
Wraps	5	4	£13.80 to £168.55

*Comparative products in terms of size and compression level

**Excludes made to measure hosiery which are priced up to £69.08

2.4 Technology user issues and preferences

People with leg ulcers may feel embarrassed by their condition and modify their behaviour to hide it. They may also be scared of hurting themselves and not go out or move as much as they would usually do. Leg ulcers can be very painful and prevent people from doing their daily activities. Having unhealed leg ulcers, especially if ulceration is complex or stays for a long time, may lead to anxiety, social isolation, depression and feeling exhausted. This can also delay treatment of other health issues if those cannot be addressed until a leg ulcer has healed.

Healing rates are likely to be significantly impacted by people not adhering to their compression treatment. One review reported that non-adherence ranged from 2% to 80% ([Moffatt et al. 2009](#)). Main reasons for non-adherence included pain, discomfort and lack of valid lifestyle advice. [Perry et al. \(2023\)](#) investigated barriers and facilitators to using and adhering to compression therapy as a treatment for venous leg ulcers. In this study, different compression products presented different challenges. For compression

bandages, key issues included some bandages falling down, unable to wear normal clothing or shoes and issues with driving. Also, a 'boot' can be worn to cover the bandages so people can shower, however not everyone was aware of this aid. The key issue noted with compression hosiery was that it could be difficult to apply. If people are unable to do this themselves or do not have a family member who could assist, this could be unpractical. Compression wraps were easy to apply, people were able to wear normal clothes and shoes, and they enabled self-care and provided flexibility. The study noted that allowing self-care could mean that they could lessen the level of compression needed. It is important to encourage the person to comply with compression therapy. This can be done by doing the following:

- Make sure that the person understands the reasons for compression therapy as well as the benefits
- Manage any associated conditions, such as for example oedema, and any potential complications such as pain or infection
- Address the person's concerns and take their preferences into account when offering compression treatment options
- Provide general lifestyle advice to promote healing such as keep mobile, elevate the legs when immobile, drink alcohol within recommended levels, stop smoking (if smoking), lose weight (if overweight or obese) and examine legs frequently for any swelling, broken skin or redness.

When deciding on which type of compression to use, factors such as the person's preference, lifestyle and likely compliance; the condition of the wound, how frequent the compression product needs to be applied and the size and shape of the leg are considered. Experts advised that typically the compression product which allows mobility and supports self-care is preferred. Experts also noted that people's previous experience of leg ulcer care may affect their preference.

3 Decision problem

Population	People aged 18 or over with a venous leg ulcer
Subgroups	<p>If the evidence allows the following subgroups may be considered:</p> <ul style="list-style-type: none"> • People with conditions that may impact self-care (such as issues with memory, manual dexterity, mobility and visibility) • People with low or high exudate wounds • People with very fragile skin • People with irregular leg shapes (such as an upside-down champagne bottle)
Intervention	<p>Compression products available to the NHS on Part IX of the Drug Tariff or NHS supply chain delivering strong or full compression (defined as 40mmHg or more) for treating venous leg ulcers. Interventions will include:</p> <ul style="list-style-type: none"> • 4-layer compression bandage systems and kits • 2-layer compression bandage systems and kits (these include 2-layer inelastic systems and 2-layer multi-component systems) • 2-layer compression hosiery • Compression wraps <p>Features within and between compression products will be explored in this assessment (see section 2.2).</p>
Comparator	A compression product or products that is considered current standard of care in the NHS (for example, based on clinical expert advice and clinical evidence)
Healthcare setting	<ul style="list-style-type: none"> • Community (including people’s homes, care homes, nursing homes, community hospitals, leg ulcer clinic) • Primary care (GP practice)
Outcomes	<p>Outcome measures for consideration may include but are not limited to:</p> <p>Intermediate outcomes</p> <ul style="list-style-type: none"> • Reduction in wound size • Changes to wound bed condition (for example slough or presence of bacterial biofilm, exudate, granulation and oedema) • Condition of peri-wound skin • Levels and reduction of oedema • Frequency of compression product changes <p>Clinical outcomes</p> <ul style="list-style-type: none"> • Percentage of wounds healed • Time to complete wound healing • Intervention related adverse events <p>Patient reported outcomes</p> <ul style="list-style-type: none"> • Health-related quality of life

	<ul style="list-style-type: none"> • Wound-related pain • Patient adherence • Ease of treatment use • Mobility <p>Costs and resource use</p> <ul style="list-style-type: none"> • Cost of the technology • Cost of supporting products (for example a hosiery applicator, a 'boot' to protect bandages when showering, a 'shoe' or an oversized sandal to help walking with bandages, or a foot, ankle or toe piece for wraps to provide full leg compression) • Cost of dressings • Cost of other resource use including: <ul style="list-style-type: none"> ○ Leg ulcer-related health care professional appointments or visits (primary, community and secondary care) ○ Planned and unplanned leg ulcer-related hospital admission or surgery ○ Staff band and time ○ Staff training ○ Clinical waste disposal <p>User preference will be assessed to identify and understand features of the technologies that influence decision making when selecting which technology to use. This is done alongside the assessment of the clinical and economic evidence.</p>
<p>Economic analysis</p>	<p>A health economic model will be developed, where possible, comprising a cost-comparison or cost utility analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The economic modelling will also consider the impact of the availability of individual bandages as well as the kits.</p> <p>The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.</p>
<p>Other issues for consideration</p>	<ul style="list-style-type: none"> • Ongoing VenUS 6 trial evaluating compression therapies for the treatment of venous leg ulcers. It is a three-arm randomised controlled trial comparing evidence-based compression (4-layer compression bandage kit or 2-layer compression hosiery) with 2-layer compression bandage kits and compression wraps. Estimated completion date of the trial is 31 August 2024. It will also include a health economic analysis. Initial results are expected before the end of 2024. • There is information on some potentially relevant economic models associated with the VenUS IV trial (2014) and in a systematic review (Layer et al. 2019). • There is known variation in practice across local formularies and care pathways in the NHS.

	<ul style="list-style-type: none"> • Dressings do not play a direct role in this aspect of venous leg ulcer management. However, it is important for clinicians to select dressings that are not adversely affected by compression products and ensure that they do not interfere with the compression of the legs. • Compression should be applied in accordance with the manufacturer’s instructions. Incorrect application can lead to uneven, inadequate or hazardous levels of pressure. This in turn can lead to pain, delayed healing, trauma or even loss of the limb. • People with venous leg ulcers who are having compression therapy using 4-layer compression bandage systems may be more likely to be immobile, have co-morbidities and more severe leg ulcers than people with venous leg ulcers that have been prescribed other types of compression products. • Data from Open Prescribing suggests that sales of individual compression bandages made up over half of the sales of compression products between May 2023 and April 2024. The flexibility in the market because of the availability of individual bandages should be explored in the economic modelling. • The NHS is aiming to reduce its carbon footprint to net zero by 2040. Wound care uses a lot of products and requires considerable travel as most care is delivered in the community. Using reusable compression products or products that allow for supported self-care may improve sustainability and may also reduce waste (Morton et al. 2022).
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3.1 Potential equality issues or considerations

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

There are several factors that can increase people’s risk for developing venous leg ulcers. These include pregnancy, obesity or being overweight, people with a history of deep vein thrombosis, varicose veins, hernias, previous ulcers or previous surgery to the leg such as hip or knee replacement. Furthermore, people with increasing age, restricted movement, sedentary lifestyle, prolonged standing and limited range of ankle function may also have a higher risk.

Venous leg ulcers occur in people from all socioeconomic groups, but ulcers take longer to heal, and recurrence rates are higher in people from lower socioeconomic groups. People with low incomes may struggle to access

appointments and people without a fixed address or in prison may struggle to access treatment. Some people, for example people with limited understanding of English language when no interpretation support is available or people with mental health conditions or a learning disability, may find it harder to understand or follow a treatment plan, which can negatively impact on healing. People who smoke, have alcohol dependency, use drugs or have nutritional deficiencies also have impaired healing.

Compression therapy should be used with caution in people with diabetes, who may have unreliable ABPIs due to arterial calcification as well as an underlying sensory neuropathy (NICE CKS, 2024). For some people with arterial insufficiency, neuropathy or advanced, unstable cardiac failure, reduced compression may be needed because strong compression can be unsafe or painful.

Some compression products such as hosiery and wraps need the person to apply the products themselves. This could be harder for people with conditions that may affect self-care for example because of issues with memory, manual dexterity, mobility or visibility.

Compression hosiery is often offered in different colours such as beige, black or white. However, some products may only be available in 1 colour (beige or white). People may prefer to choose hosiery that most closely matches their skin tone if this is available. Compression products with latex are not suitable for people with latex allergy.

Age, disability, sex, race, pregnancy and maternity are all protected characteristics under the Equality Act (2010).

4 NICE Team

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Appendix A Related NICE guidance

- [Automated ankle brachial pressure index measurement devices to detect peripheral arterial disease in people with leg ulcers](#) (2023). NICE diagnostics guidance DG52.
- [Compression stockings](#) (2022). NICE Clinical Knowledge Summary.
- [Leg ulcer – venous](#) (2024). NICE Clinical Knowledge Summary.
- [Shared decision-making](#) (2021). NICE guideline 197.
- [Varicose veins](#) (2013). NICE clinical guideline 168.

Appendix B Abbreviations

ABPI	Ankle Brachial Pressure Index
BNF	British National Formulary
CKS	Clinical Knowledge Summary
LSA	Late-stage assessment
NWCSP	National Wound Care Strategy Programme