

Health Tech Programme

Medical Technologies Advisory Committee (MTAC)

Compression products for treating venous leg ulcers: late stage assessment – 2nd meeting

19 June 2025

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The following documents are made available to the Committee:

1. Cover sheet
2. Public consultation comments and draft responses on the draft guidance [no ACIC]
3. Addendum to the External Assessment Report (EAR) [no ACIC]

HealthTech Programme

GID-HTE10048 Compression products for treating venous leg ulcers: Late-stage assessment

Draft Guidance comments

There are 53 comments from 4 consultees, including companies (n=3) and other stakeholders (n=1). The comments are reproduced in full, however, duplicate comments have been merged, and some comments have been split as they contain multiple issues covering separate themes. The final 37 comments have been arranged in the following themes:

- Recommendations: comments 1 to 9
- The technology: comments 10 to 12
- User preferences: comments 13 to 17
- Clinical evidence: comments 18 to 22
- VenUS 6 study: comments 23 & 24
- Economic modelling: comments 25 to 33
- Equality considerations: comments 34 & 35
- Factual inaccuracy: comments 36 & 37

Comment no.	Consultee	Section no.	Comment	Response
Recommendations				
1.	Consultee 1 L&R medical	1.4 – why the committee made these recommendations	Explicit inclusion of compression wraps as a standalone category in scope, considering their unique adjustability and suitability for patient self-management.	<p>Thank you for your comment.</p> <p>Compression wraps are included as a standalone category in the scope. Please see the scope for further information: https://www.nice.org.uk/guidance/gid-hte10048/documents/final-scope</p>
2.	Consultee 3 Urgo Ltd	1.4 – why the committee made these recommendations 1.4 – what information is needed 3.25	Providing the patient has the dexterity to apply themselves, otherwise where hosiery is used for treatment of VLU, patients often have their hosiery changed along with dressing changes by nurses. Therefore, compression hosiery is only cost effective if a nurse is not needed to change the dressing or apply the hosiery	<p>Thank you for your comment.</p> <p>The EAG agrees that self-application is dependent on dexterity and therefore the extent of self-care that is possible may vary between patients.</p> <p>The EAG model did not assume no nursing assistance for 2-layer compression hosiery (2LCH). The EAG estimated 1.60 dressing changes per week for bandages, with a band 5 nurse. For compression wraps (CWs) and 2LCH this was assumed to be 1.11 per week, with a</p>

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				<p>band 3 or 4 nurse (see section 7.2.5.1 in the EAR). For 2LCH and CWs the EAG assumed that some dressing changes would be done by someone other than a healthcare professional, this may be the patient themselves or for example a carer. With this assumption, the EAG noted that the fact that two- and four-layer compression bandages (2LCB, 4LCB) were shown to be on average more expensive over the five-year time horizon than CWs and 2LCH and was potentially largely driven by the more frequent dressing changes with a more highly qualified nurse required for 2LCB and 4LCB compared with the CW or 2LCH.</p> <p>For clarity, the sections in guidance that this comment refers to have been amended to reflect that in the economic modelling the 2LCH also had visits, but that the compression bandaging had more visits:</p>

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				<p>“Economic modelling suggests that compression hosiery, which enables self-management, is cost effective compared with compression bandaging, which relies on more regular visits from a nurse to change the dressing.”</p> <p>The committee discussed that there are many factors which may impact on a patient’s ability to self-care, aside from patient dexterity. The scope included multiple subgroups including 1) People with conditions that may impact self-care (such as issues with memory, manual dexterity, mobility and visibility), 2) people with low or high exudate wounds, 3) people with very fragile skin, and 4) people with irregular leg shapes (such as an upside-down champagne bottle). No evidence was identified in the EAG’s clinical evidence review, and the committee emphasised the importance of</p>

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				analysing effectiveness in these subgroups, which has been added to section 3.28 of the guidance.
3.	Consultee 3 Urgo Ltd	1.4 – what information is needed	<p>This appears to be contradictory to earlier statements and statements in Why the committee made these recommendations.</p> <p>Please remove this in entirety or re-word this as per the statement in Why the committee made these recommendations: "there is limited evidence on the clinical effectiveness of compression wraps compared to 2LCH, 2LB, 4LB"</p>	<p>Thank you for your comment.</p> <p>These sections have been updated following the committee's consideration of the pre-print publications related to the VenUS 6 study.</p>
4.	Consultee 3 Urgo Ltd	1.4 – what information is needed	<p>This seems to contradict the comment in the section "What information is needed: More information is needed to determine whether compression wraps are clinically, and cost effective compared with compression hosiery or compression bandaging"</p> <p>Statement in "Why the committee made these recommendations" states "but there is limited evidence on the clinical effectiveness of compression wraps compared to these products (2LCH, 2LB, 4LB)". Please remove the reference to compression wraps here</p>	<p>Thank you for your comment.</p> <p>Please see the response to comment 3.</p>
5.	Consultee 4 Essity	1.4	Joint decision making is essential - would add in here that patient choice is needed but the level of	Thank you for your comment.

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			compression is clinically driven. The higher the compression level the patient may perceive to be uncomfortable then lower compression classes. Essity believe this need to be clear in this section	<p>Section 1.4 'What this means in practice' also describes 'Considerations for healthcare professionals.' This section states that 'These recommendations do not replace clinical reasoning. If more than one type of compression product is clinically appropriate, the choice of compression product should be based on the preferences of the person with the leg ulcer and cost effectiveness, taking into account the factors listed in recommendation 1.4.'</p> <p>The committee has considered this comment and no changes to the guidance have been made.</p>
6.	Consultee 4 Essity	1.4	In this section will need to be clear that at times products may not be as aesthetically pleasing but may be required for the phase of care i.e a ready to wear product isn't suitable for limbs that are misshapen. The HCP would need to make this clear to not cause adverse events to the care	<p>Thank you for your comment.</p> <p>Please see the response to comment 5.</p> <p>Furthermore, under 'considerations for people with venous leg ulcers' it is</p>

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				<p>made clear that they should be involved when deciding which compression product to use and that information should be provided on the compression product that is being prescribed and, where possible, offered options that meet their needs.</p> <p>The committee has considered this comment and no changes to the guidance have been made.</p>
7.	Consultee 4 Essity	1.4 – what information is needed	Waterproof protectors are not readily available on most formularies and would require patients to purchase themselves	<p>Thank you for your comment.</p> <p>Following committee discussion, this sentence under ‘considerations for healthcare professionals’ has been amended to add that this can be done ‘through formularies or GP prescribing if appropriate’.</p> <p>Furthermore, amendments have been made to ‘considerations for people with venous leg ulcers’ to reflect that patients should be made aware of how they can get access to</p>

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				products that support the use of compression products, instead of asking for them.
8.	Consultee 4 Essity	1.4 – what information is needed	Is the intention to wait for Venous 6 before making this as understanding this has been looked into with evidence to back up use of Wraps ?	<p>Thank you for your comment.</p> <p>Since the first committee meeting, the VenUS 6 team have published the:</p> <ul style="list-style-type: none"> the VenUS 6 clinical trial (Arundel et al, 2025) the network meta-analysis and cost-effectiveness analysis (Phung et al, 2025) <p>These were published as pre-prints in the Lancet on the 1st of June 2025 and are subject to peer-review. The EAG reviewed the two pre-prints in their addendum. The guidance has been updated to reflect the VenUS 6 information in the public domain.</p>
9.	Consultee 4 Essity	Are the recommendations sound and a	Partly - There is not enough evidence to determine whether price variation is justified for compression wraps over other compression products.	Thank you for your comment.

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		suitable basis for guidance to the NHS?	<p>The consideration needs to be made more clear that price variation will take place with the 1.3 and 1.4 of the recommendations. Company's will wraps have are designed for patients with individual needs.</p> <p>To be noted in recommendation of cheapest products Essity would like to highlight - In VLU kits options are available through certain product ranges to have zips in different places to reduce pain and increase ease of applying supporting self care. The manufacturers have to create more bespoke items as "one fits all" does not work in this treatment. Companies that offer a wider range of options and sizes should be recognized as this will cost more in manufacturing different styles to increase patient satisfaction. Also consideration needs to be take into length of use of the product.</p> <p>The cheapest VLU kit with over 5% market share Altipress® stockings comes in - S, M, L, XL, XXL, short, regular and long. Altipress® stockings are designed to last for a minimum of 3 months if cared for correctly.</p>	<p>For this late-stage assessment it was agreed that the 'features' within this assessment were the four types of compression products as listed in the final scope. The variation of features within a product type (colour, marking) was expected to have less impact on their effectiveness.</p> <p>Section 2.2 of the guidance has been amended to be clear that the variation of features within a product type was excluded from this assessment.</p> <p>Please see the response to comment 26 for length of use, and comment 31 for made-to-measure products.</p> <p>During resolution, the company producing the Altipress hosiery highlighted that the IFU for Altipress hosiery states that they are 'designed to last up to 6 months if cared for as per the manufacturer's instructions'.</p>

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			Compared to Jobst UlcerCare - S, M, L, XL, XXL, XXXL, XXXXL; outer stocking available with or without zipper in beige or black; zipper can be placed left or right: Liner pack also available containing three liners. JOBST UlcerCare have a six month guarantee against garment failure caused by manufacturing or material defect	
The technology – strong compression				
10.	Consultee 1 L&R medical	2.1	Now the guidance states its only considering strong compression (at least 40mmHg) has the cost modelling being adapted to this too? ReadyWrap® which delivers strong compression is significantly more cost effective than other wraps previously considered for this guidance. Is this reflected in the latest economic data?	<p>Thank you for your comment.</p> <p>The economic model included evidence for time to healing, which was based on the EAG NMA. As explained in section 5.5.1 of the EAR, this NMA was conducted by the VenUS 6 team, and the studies with aggregate data included in the NMA is presented in table 7 of the EAR. At the EAG's request, the VenUS 6 team provided a scenario analysis separating 2LCH and 4LCB (EAG NMA). Section 7.2.4.1 of the EAR discusses the time to healing inputs and further detail of VenUS 6 NMA can be found in Phung et al. (2025).</p>

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				<p>Please also see the response to comment 11.</p> <p>NHS Drug Tariff prices for ReadyWrap were £91.87 (calf, including liner), £40.33 (foot), £47.04 (toe), £48.64 (knee) and £102.68 (thigh). The compression wrap price in the EAG report (Table 17) is £111.58, which is comparable to the prices for the ReadyWrap calf and thigh. The EAG's analysis did not consider individual products but classes of product. A product that is lower cost than others within its class and of at least equal effectiveness will, by definition be more cost-effective than others.</p>
11.	Consultee 3 Urgo Ltd	2.1	<p>This is factually inaccurate. The scope was broadened to include products that delivered 30 - 40mmHg</p> <p>The assessment does NOT only include products that deliver at least 40mmHg at the ankle and are used for treating venous leg ulcers.</p>	<p>Thank you for your comment.</p> <p>The decision problem includes products that deliver strong compression. Definitions of strong compression differ internationally.</p>

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			Committee Papers, 2. Clinical Effectiveness p. 4	<p>Because of the limited evidence, the EAG used a pragmatic approach and included a broader evidence base (including compression levels of 30-40mmHg), to ensure that evidence reflected the range of comparisons between scoped compression product types. This pragmatic approach was accepted to be relevant to the decision problem by the committee in the first Medical Technology Advisory Committee meeting.</p> <p>As mentioned above, there is international variation in definitions of strong compression, and clinical expert advice was that the level of compression achieved varies considerably between patients.</p> <p>One included study (Dolibog et al. 2014) conducted in Poland used higher compression levels than usually used in the UK. It included</p>

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				<p>compression hosiery delivering at least 60mmHg and 4-layer compression bandages that deliver at least 45mmHg.</p> <p>Of the 15 studies included in the EAG's review, 3 studies (Dolibog et al. 2014; Finlayson et al. 2014; Ashby et al. 2014) included products delivering 30 to 40 mmHg, comprising a small part of the evidence base. Therefore, variation in definitions of strong compression does not mean that the evidence base as a whole is poorly aligned to the scope.</p> <p>Section 3.11 of the guidance has been amended to reflect the pragmatic approach the EAG has taken in their assessment.</p>
12.	Consultee 4 Essity	2 & 2.2	This assessment does not include compression products which are used for maintenance following ulcer healing or those used before or after surgery.	<p>Thank you for your comment.</p> <p>Section 2.1 describes that the scope includes only compression products</p>

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			The NWCSP recommends use of >20mmHg when waiting for specialist intervention. If not included in LSA could this be made clear that its out of scope ? https://www.nationalwoundcarestrategy.net/wp-content/uploads/2024/07/NWCSP-Leg-Ulcer-Recommendations-final-version-15.07.2024.pdf	which deliver at least 40 mmHg of pressure at the ankle and are used for treating venous leg ulcers. Therefore, products which deliver compression aligned with the NWCSP's recommendation to use >20mmHg compression when waiting for specialist intervention are out of scope. Please also see the response to comment 11.
User preferences				
13.	Consultee 1 L&R medical	3.8	The guidance does not sufficiently consider how difficult-to-apply therapies lead to non-compliance, especially among elderly or mobility-limited patients. Compression wraps, which are user-adjustable and reusable, address compliance issues more effectively than traditional methods.	Thank you for your comment. The EAG agreed that it received some clinical advice that compression wraps may make it easier for patients to self-care. This could address compliance issues, although this will vary between patients. Ultimately, the appraisal has to consider the average patient as it is not possible to capture all possible sources of variation. There is limited

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				<p>evidence on adherence to treatment for compression wraps: Blecken et al. (2005) found 100% adherence for both wraps and 4-layer compression bandages, Stather et al. (2021) found lower discontinuation rates (5% vs 15%) for wraps vs short stretch bandages, and while adherence was a secondary outcome in VenUS 6, no results for this outcome are reported in the Arundel et al. (2025) preprint.</p> <p>The committee discussed that the additional value of compression wraps is unclear because the VenUS 6 clinical trial showed that time to healing was slower compared with the other compression products. Clinical experts noted that compliance to treatment can influence effectiveness and that for some patients compression wraps may be the only suitable option. The committee asked for more evidence to address some of the remaining</p>

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				uncertainty for compression wraps, including patient selection, clinical performance and compliance to treatment. This is reflected in section 'what information is needed', and section 3.27 and 3.28 of the guidance.
14.	Consultee 1 L&R medical	3.27	<p>The document does not recognise that wrap systems often require less intensive training compared to multi-layer systems.</p> <p>Compression wraps can put applied with relative ease of use for both patients and carers, especially in community and home settings, which could enhance uptake and reduce staffing pressure.</p>	<p>Thank you for your comment.</p> <p>In the external assessment report, table 2 presents the anticipated benefits of features of compression products for people with venous leg ulcers.</p> <p>The committee noted that some of these anticipated benefits are not reflected in the current evidence base. It recommended to collect evidence on the ease of application for compression wraps alongside patient and clinical performance outcomes (see section 'what information is needed').</p>

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15.	Consultee 3 Urgo Ltd	3.6	The LSA focusses on Band 3 – 5 nurses with these band nurses being used on the cost modelling to determine cost impact, however, no band 3 – 5 nurses were included in the clinical experts or user preference report.	<p>Thank you for your comment.</p> <p>NICE acknowledged that a limitation of the user preference assessment and patient survey is volunteer bias. Users and patients volunteered to take part in the relevant activities, and it is likely that the sample of participants is not fully representative of the wider populations. NICE publicly advertises its specialist committee member roles and encouraged companies, professional organisations and patient organisations to nominate or share this opportunity. In addition to this, NICE held a public consultation on the draft recommendations and associated documents. So, other users (healthcare professionals) and patients had the opportunity to provide additional comments. The user preference assessment is intended to compliment the clinical and economic assessments by</p>

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				providing a transparent insight into the preferences identified by the users involved in the assessment.
16.	Consultee 4 Essity	3.8	A breakdown of associated cost would be useful to allow industry to ensure the right evidence and product developments can be prioritised	<p>Thank you for your comment. Section 3.8 refers to the user preference report. It reports the criteria developed and ranked by the users when choosing which compression product to use.</p> <p>The associated costs are considered in the EAG's economic modelling, which is reported in table 17 of the external assessment report.</p>
17.	Consultee 4 Essity	3.8	<p>The number of product disposed of using 4/2layer is considerable impact in line with NHS drive.</p> <p>Major crackdown on NHS waste announced HCSA</p>	<p>Thank you for your comment.</p> <p>Sustainability was identified as a criterion in the user preference report. Even though users felt that sustainability is an important issue for delivering a net zero NHS, and that compression products such as hosiery and wraps can reduce not only the carbon footprint but also product waste (Morton et al. 2022), it</p>

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				<p>was ranked as the least important criteria by 7 users when it comes to choosing a compression product.</p> <p>The committee discussed the importance of delivering a net zero NHS. It asked that information is collected on the impact of using the different compression product types on sustainability. This has been added to section 3.28</p>
Clinical evidence				
18.	Consultee 1 L&R medical	Has all of the relevant evidence been taken into account?	The guidance has only considered RCTs regardless of size of study. However evidence has been submitted with much larger patient cohorts that provide much more accurate information regarding patient suitability and compression wrap usage. So this is 100% a missed opportunity and misrepresentation of the evidence available surrounding ReadyWrap in particular.	<p>Thank you for your comment.</p> <p>The EAG's approach to study selection and prioritisation was set out in the protocol. The focus of this LSA is on comparing compression product types rather than individual products as described in the decision problem presented in the scope.</p> <p>Both of the studies supplied by the company (Hallas-Hoyes et al. 2021; Thomas et al. 2024) used a single-</p>

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				arm design, so were not suitable to be prioritised as evidence in this appraisal, as it is not possible to determine that the observed effect is due to the intervention. Furthermore, Thomas et al. (2024) included people with lymphedema which was outside of the scope for this LSA.
19.	Consultee 2 Individual	Has all of the relevant evidence been taken into account?	Yes.	Thank you for your comment.
20.	Consultee 4 Essity	Has all of the relevant evidence been taken into account?	Please consider https://journals.cambridgemedia.com.au/wpr/volume-32-number-3/adjustable-velcro-compression-devices-compared-4-layer-compression-bandages-treatment-venous-leg-ulcers-and-optimisation-patient	Thank you for your comment. The EAG noted that the title and abstract of this paper refers to adjustable Velcro compression devices. The term 'compression wrap' is not used and therefore it was excluded at screening stage. However, clinical experts have advised that adjustable Velcro compression devices are compression wraps. This study does not change the overall results for

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				compression wraps. It was not included in the network meta-analysis because it is a prospective cross-over study and not a randomised controlled trial. Please see the response to comment 24.
21.	Consultee 3 Urgo Ltd	Has all of the relevant evidence been taken into account?	Evidence for products that DO NOT deliver strong compression (at least 40mmHg at the ankle) should be excluded	Thank you for your comment. Please see the response to comment 11.
VenUS 6 study				
22.	Consultee 3 Urgo Ltd	Has all of the relevant evidence been taken into account?, 3.12 & 3.16	Use of unpublished, non-peer reviewed and redacted information from Venus VI prevents any commentary on factual inaccuracies or probability of bias. We request that the information in Venus VI that has been used by EAG, be made public in the interests of fairness.	Thank you for your comment. Please see the response to comment 8.
23.	Consultee 4 Essity	3.3	Could the results of Venous 6 support this over the use of compression wraps for patients requiring bandaging ? Is the recommendations taken into account ?	Thank you for your comment. Please see the response to comment 8.

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24.	Consultee 1 L&R medical	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Not in our opinion as previous guidance (based on literature reviews including RCTs) stated that compression wraps were a cost effective solution. Based on the data and justification previously, why the sudden u-turn?	<p>Thank you for your comment.</p> <p>The current evidence base for compression wraps consists of 2 RCTs:</p> <ul style="list-style-type: none"> • Blecken et al. (2005) is an RCT based in the USA and included 12 people with venous leg ulcers (VLUs). They found similar rates of wound healing and wound size reduction for compression wraps and 4-layer bandaging. • Stather et al. (2021) is a UK RCT of 40 people with VLUs. They also found comparability between compression wraps and short stretch bandaging in terms of % wounds healed, time to healing and quality of life (at 1 and 6 months) <p>Since then, the VenUS 6 trial has been conducted, and at the time of the first committee discussion in</p>

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				<p>March 2025 the results were not in the public domain. However, since then the results have been made publicly available as pre-prints in the Lancet.</p> <p>The VenUS 6 trial, a UK RCT of 637 people with VLUs, compared evidence-based compression (EBC, i.e. two-layer compression hosiery or 4-layer compression bandages) with compression wraps and with 2-layer compression bandages. They found that time to healing was slower in the compression wrap group compared with both evidence-based compression (hazard ratio (HR): 0.78; 95% CI 0.61 to 1.00; p = 0.046) and the 2-layer bandage groups (HR: 0.79; 95% CI 0.61 to 1.01; p = 0.056) respectively. There were no statistically significant differences in cumulative incidence of ulcer infection, ulcer deterioration, skin deterioration or new/incident ulceration or in participant quality of</p>

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				<p>life. Therefore, there is variability in whether clinical evidence considers compression wraps to roughly equivalent to other, more established forms of compression, or less effective.</p> <p>The EAG report concluded that compression wraps were likely to be the most cost-effective option and there was no maximum economically justified price for any other option. The EAG urged caution because of the limitations of the analysis, and the small absolute differences in outcomes between product types.</p> <p>The EAG has submitted an addendum exploring the differences in methodology and results between the decision models favoured by the EAG and the VenUS 6 team. The decision models are based on 2 different network meta-analysis (NMA) approaches. The EAG preferred to allow four-layer</p>

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				compression bandaging and two-layer compression hosiery to be independent nodes, whereas VenUS 6 preferred to combine them as one 'evidence-based compression node'. This led to small non-statistically significant differences in clinical effectiveness in favour of compression wraps in the EAG preferred NMA and against compression wraps in the VenUS 6 preferred NMA. In turn, because costs are similar between treatments, this led to opposite conclusions in the EAG preferred and VenUS 6 preferred decision models. The EAG preferred decision model supported compression wraps, whereas the VenUS 6 preferred decision model did not.
Economic modelling				
25.	Consultee 1 L&R medical	3.18	Wraps perceived as more costly: The modelling may overstate upfront costs of wraps without accounting for long-term cost savings from reduced nurse visits, improved adherence, and fewer complications.	Thank you for your comment. Section 3.18 reports on the model structure. There is currently no

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			Surely scenario-based cost modelling that includes self-care benefits and reduced long-term healthcare utilisation.	<p>reference in the draft guidance that states that CWs are perceived as more costly. Section 3.21 reports on 'Costs include compression product cost and resource use cost.'</p> <p>The EAG stated that their decision modelling includes expected costs associated with nurse visits whilst the ulcer is healing, therefore takes into account any reductions associated with wraps (see Table 17 of EAG report). These factors were included in the EAG model by factoring number of nurse contacts with the different product types.</p>
26.	Consultee 4 Essity	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	Is the consideration taken into the length of use of VLU Kits. Some manufacturers have 3 months vs 6 month use. Please see comment below [refers to comment 9].	<p>Thank you for your comment.</p> <p>In the EAG's economic model, the length of use of the different product categories are taken into account. Quantities were omitted from the EAG report but can be calculated by dividing the costs reported in Table 17 by the unit costs reported in</p>

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				<p>Table 13 of the EAG report. For example, the mean number of 4LCBs required per patient is 53.3, whilst for compression hosiery this is 1.06.</p> <p>The EAG's base case assumed that 2-layer compression hosiery (2LCH) would last for 3 months while the venous leg ulcer was unhealed. Their assumption was that all patients would use compression hosiery for maintenance upon healing to prevent recurrence. This maintenance hosiery would last 6 months. Taking into account time to healing, the EAG model assumes 10.08 units over the 5-year time horizon at a cost of £157.98 based on the Drug Tariff costs.</p> <p>If 2LCH is assumed to last 6 months during the unhealed stage, then over the 5 years the count reduces to 8.87, or a cost of £138.99.</p>

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				<p>The difference in the costs is a reduction of £18.99, which is insufficient to change the cost-effectiveness results; specifically, the ordering of net monetary benefit or net health benefit does not change.</p> <p>Section 3.18 in the guidance has been changed to reflect the assumption that 2LCH lasts for 3 months instead of 6 months for an unhealed venous leg ulcer.</p>
Economic modelling – nurse banding and healthcare visits including costs				
27.	Consultee 3 Urgo Ltd	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? 1.1 & 3.21	<p>There is no evidence that states the band of nurse that can apply, change or remove either 2LB, 4LB, 2LCH, CW and there is no evidence that determines that a Band 5 nurse is needed to apply, remove or change 2LCB or 4LCB.</p> <p>This is determined by the healthcare professionals local trust and policies. 2LCB & 4LCB can be applied by non-registered health practitioners as per trust policies and protocols, please see evidence/information below:</p>	<p>Thank you for your comment.</p> <p>The EAG based its position on clinical expert advice regarding the band of nurse that would be needed in routine clinical practice to apply each type of compression product. The EAG was advised that initial appointments would be Band 5 nurse, but Band 3 or 4 staff could do follow-up appointments, although Band 5 would be usual for four-layer</p>

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			<ul style="list-style-type: none"> NHS Brighton & Hove NHS East Sussex, NHS West Sussex The Health care support worker Band 1-4 , Competency, Skills and Competency Framework. Competency-Skills-and-Qualification-Framework.docx p.46-47 Appendix 1:4 – Compression Bandaging Competency Framework Assessment for Non-Registered Practitioners, Multi-Layer / Short-Stretch / Long-Stretch ‘Applies bandage system appropriately according to taught theory and manufacturer’s instructions Applies 4 layer bandage system (Put N/A if not assessed in this bandage system) Applies short stretch bandage system (Put N/A if not assessed in this bandage system) Applies K-two bandage system (Put N/A if not assessed in this bandage system) 	<p>compression bandages as applying these is much more technical.</p> <p>Following external assessment report consultation, the EAG conducted a scenario analysis that showed that the nurse banding did not materially affect the cost effectiveness results. This is reported in section 3.21 of the guidance.</p> <p>The band of nurse that can apply the different compression products is not specified in the guidance.</p>

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			<p>Applies Coban 2 bandage system (Put N/A if not assessed in this bandage system)</p> <p>All the questions above are part of a competency assessment for Band 1 – 4 nurses. Therefore, the statement on band 5 nurses needed to apply 2LCB and/or 4LCB are incorrect and the cost impact as part of this LSA is incorrect.</p> <ul style="list-style-type: none"> Lincolnshire Training Hub <p>Nursing Associate General practice Competencies</p> <p>Career-Start-NA-General-Practice-Competencies-Sept23.pdf</p> <p>p.2 Compression bandaging. “NAs must work under the supervision of GPNs. GPNs must create care plans and initiate changes. NAs must complete relevant training such as compression, hosiery assessment and measuring”.</p> <p>ALL healthcare professionals need to undertake competency assessment for application of</p>	

Comment no.	Consultee	Section no.	Comment	Response
			<p>compression products that include 2LCB, 4LCB, 2LCH, CW irrespective of their banding. A band 3 or 4 nurse, if they have not completed their competencies and/or undergone adequate training would NOT be able to apply 2LCH or CW.</p> <p>Please see evidence below on competency/training requirement for applying compression wraps and for applying all types of compression.</p> <ul style="list-style-type: none"> • Cheshire Formulary <p>Guidance to providing compression hosiery Layout 1</p> <p>p. 4 "Compression wraps can be applied by any qualified nurse who has had the training in that wrap system and understands the underlying principles of compression. Correct patient selection is required, ensuring the patient has the understanding and dexterity to apply the product. All wrap systems need to be checked on each dressing change for correct fit as a reduction in oedema can happen quickly. Products need to be reordered or refitted as appropriate."</p>	

Comment no.	Consultee	Section no.	Comment	Response
			<ul style="list-style-type: none"> Berkshire Healthcare NHS Foundation Trust “On completion of initial and reassessment of competencies (2 yearly) an eAcknowledgement needs to be completed on ESR.eg Ulcer Assessment Competency”. Cornwall Partnership NHS Foundation Trust Transforming wound care Cornwall Partnership NHS Foundation Trust “Our training aim is to ensure all staff who provide lower limb wound care have the competence, knowledge and confidence to deliver care within the National Wound Care Strategy Programme recommendations.” <p>Please remove this reference and re-calculate the cost savings with the same band nurse across 2LCB, 4LCB, 2LCH & CW</p>	
28.	Consultee 3 Urgo Ltd	3.21 & 3.25	Is the cost of healthcare visits related in entirety to the venous leg ulcer? There will be many instances where the patient is being visited for 2 or more nursing activities (i.e. catheter care and a leg ulcer).	<p>Thank you for your comment.</p> <p>The cost of healthcare visits were assumed entirely related to venous</p>

Comment no.	Consultee	Section no.	Comment	Response
			When the leg ulcer is healed, the patient will still be having a nursing visit for catheter care, therefore, there will be no reduction in the number of nursing visits. Have these scenarios been factored into the assumptions and modelling?	leg ulcers. The scenarios suggested by the commenter were not factored in the modelling. The EAG considers that a dressing change, particularly for 4LCB and 2LCB are relatively time-consuming activities thus there will still be a reduced time use associated with their avoidance.
Economic modelling – model inputs				
29.	Consultee 1 L&R medical	3.20	<p>Outcomes limited to traditional metrics: Metrics like “time to healing” and “cost per healed ulcer” are used without factoring in improved quality of life or patient autonomy with wraps.</p> <p>We recommend the inclusion of metrics like ease of self-application and patient satisfaction.</p>	<p>Thank you for your comment.</p> <p>The commenter refers to the model inputs rather than outputs. The outcome of the economic analysis is incremental cost per Quality Adjusted Life Year gained (please see external assessment report section 7.3). The driver of patient quality of life was assumed to be ulcer healing alone. Patient satisfaction and ease of application are very challenging to capture within a decision model and are generally considered alongside the results in a qualitative manner.</p>

Comment no.	Consultee	Section no.	Comment	Response
				The committee has considered this comment and no changes to the guidance have been made.
30.	Consultee 3 Urgo Ltd	Are the recommendations sound and a suitable basis for guidance to the NHS? 3.20	<p>In the Committee papers it states: "Dressings were assumed to cost £0.57 each (BNF)". P.19</p> <p>Dressing costs will differ for 2LCB, 4LCB vs 2LCH and CW both in the individual dressing costs and accounting for the frequency of dressing change. Adhesive dressings are often used under 2LCH & CW's so as the dressing remains in place when the patient removes the wraps or hosiery. Patients will change their dressing more frequently with 2LCH and CW as they are able to access the wound dressing when they remove their 2LCH or CW. For 2LCB & 4LCB, the dressing is only changed when the compression bandaging is changed, and a non-adhesive dressing is typically used. The price difference between a non-adhesive and adhesive dressing is substantially different with an average priced adhesive dressing being more than 50% the cost of an average non adhesive dressing. The price difference between a non-adhesive and adhesive dressing including more frequent dressing changes</p>	<p>Thank you for your comment.</p> <p>The EAG acknowledges this as a limitation but considers the results to be insensitive to this. For example, the EAG's model estimated a total of 53.3 dressing changes to heal an ulcer. A 50% increase in cost of dressings would equate to an extra £15-£16, which would not be sufficient to change the results of the analysis.</p> <p>The committee has considered this comment and no changes to the guidance have been made.</p>

Comment no.	Consultee	Section no.	Comment	Response
			for patients using 2LCH & CW, should be factored into the costs.	
31.	Consultee 3 Urgo Ltd	Are the recommendations sound and a suitable basis for guidance to the NHS?	Made to measure (MTM) leg ulcer hosiery kits account for around 60% of leg ulcer hosiery usage, however, this has not been accounted for in the cost modelling. Patients with abnormal limb shapes will need MTM which costs significantly more than ready to wear (MTM costs >50% more than ready to wear) and this will significantly reduce the cost effectiveness of 2LCH	<p>Thank you for your comment.</p> <p>The EAG confirmed that made to measure kits were excluded from the decision modelling, which is reported in section 9.2 of the external assessment report.</p> <p>Section 2.1 has been amended to reflect that made-to-measure (MTM) compression hosiery is excluded. Clinical experts noted that MTM compression hosiery is mostly used for long term limb management, and not for first line compression hosiery treatment.</p>
32.	Consultee 3 Urgo Ltd	1.4 – why the committee made these recommendations 1.4 – what information is needed	Has made to measure (MTM) leg ulcer hosiery kits been included in the cost modelling? Patients with abnormal limb shapes will need MTM which costs significantly more than ready to wear (MTM costs >50% more than ready to wear).	<p>Thank you for your comment.</p> <p>Please see the response to comment 31.</p>

Comment no.	Consultee	Section no.	Comment	Response
			If MTM has not been included, please clearly state this as a limitation to the cost modelling	
33.	Consultee 3 Urgo Ltd	3.22 & 3.25	Has made to measure (MTM) leg ulcer hosiery kits been included in the cost modelling? Patients with abnormal limb shapes will need MTM which costs significantly more than ready to wear (MTM costs >50% more than ready to wear)	Thank you for your comment. Please see the response to comment 31.
Equality considerations				
34.	Consultee 1 L&R medical	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	Missed opportunity to highlight equity gains: The potential of compression wraps to promote equity (e.g., among those with limited access to regular care or physical limitations) is not fully explored. We recommend additional analysis of how compression wraps improve access and outcomes across different socioeconomic or demographic groups.	Thank you for your comment. The EAG discussed equity considerations in detail in its report (EAG Report section 4). Equity gains were not a scoped outcome, so they were not considered in the modelling. Further, there wasn't available evidence for the scoped subgroups. Equality considerations are discussed in section 3.9 and 3.10 in the guidance. Please see the response to comment 2.

Comment no.	Consultee	Section no.	Comment	Response
35.	Consultee 2 Individual	Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?	No.	Thank you for your comment.
Factual inaccuracy				
36.	Consultee 3 Urgo Ltd	1.4 – what information is needed	<p>Please change this word to COMPRESSION</p> <p>The word dressing should be replaced with COMPRESSION to avoid confusion. The recommendations are only relating to Compression and not for dressings used under compression</p>	<p>Thank you for your comment.</p> <p>The word dressing was mentioned twice in section 1.4: 'what this means in practice' in the guidance, and these have now been replaced with compression product.</p>
37.	Consultee 3 Urgo Ltd	3.25	<p>The word dressing should be replaced with COMPRESSION to prevent confusion.</p> <p>The subject of these recommendations is the COMPRESSION and not the dressing used under the compression products</p>	<p>Thank you for your comment.</p> <p>The word dressing was mentioned once in section 3.25 of the guidance which has now been replaced with compression product.</p>



Compression products for treating venous leg ulcers: late-stage assessment [GID-HTE10048]

Addendum #1

June, 2025

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1. INTRODUCTION

The purpose of this addendum is to comment on two manuscripts supplied by the VenUS 6 team and discuss differences between the VenUS 6 base case and the EAG base case. These manuscripts were published on the 1st of June 2025 as pre-prints with the Lancet, and include the VenUS 6 clinical trial results and the VenUS 6 network meta-analysis and cost-effectiveness analysis.^{1,2}

2. VENUS 6 TRIAL MANUSCRIPT

Information about the VenUS 6 trial design is summarised in the EAG report (Section 5.5). In brief, VenUS 6 is a parallel group RCT conducted in a UK setting. It compared three types of compression - strong compression (40mmHg pressure at the ankle): i) compression wraps, ii) two-layer bandage, or iii) 'evidence-based compression' (two-layer hosiery or four-layer bandage). Participants will be followed up for a maximum of 12 months. The primary endpoint is time-to-healing, measured in days since randomization, supplemented by a range of secondary endpoints (described in the EAG report, Section 5.5). As VenUS 6 was a pragmatic trial, participants and clinical staff were not blinded, although outcome assessors were blinded. The key research question was whether two-layer bandages and/or compression wraps are a clinically effective treatment compared with 'evidence-based compression' for time to healing of venous leg ulcers.

The study was conducted between 03.02.2021 and 31.08.2024 across 33 UK primary, secondary and community NHS trusts. Adults with a venous leg ulcer appropriate for compression therapy were eligible for inclusion. Participants were randomised 1:1:1 to be offered compression wraps, a two-layer bandage or evidence-based compression (two-layer hosiery or a four-layer bandage). A total of 637 participants were randomised across the three arms: compression wraps (n=213), two-layer bandage (n=211) or evidence-based compression (n=213). Across groups, 55% of participants were male, the mean age was 70.3 (range 24.6 to 97.0) years and the majority (95%) of included participants were of white ethnicity. There was no evidence of significant baseline imbalances across groups. Treatment switching was common across groups, reflecting routine clinical practice, although patterns of treatment receipt were generally similar across the three groups. Some procurement delays were also encountered. However, 95% of the 522 participants that completed follow up at one month reported current or previous use of the treatment allocated to their arm.

The key finding of the manuscript is that the primary endpoint of time-to-healing was inferior (i.e. slower) for the compression wrap arm than the 'evidence-based compression' arm (hazard ratio (HR): 0.78; 95% CI 0.61 to 1.00; p = 0.046) and the two-layer bandaging arm (HR: 0.79; 95% CI 0.61 to 1.01; p = 0.056). The EAG did note that statistical significance was not reached for the comparison between compression wraps and two-layer bandaging. No between-arm differences were statistically significant for secondary outcomes (including reference leg healing, cumulative incidence of ulcer infection, ulcer deterioration, skin deterioration or

new/incident ulceration over either 6- or 12-month time horizons. While point estimates versus 'evidence-based compression' for reference leg healing favoured two-layer compression bandages, the comparison was not statistically significant and the EAG did not consider the difference to be meaningful. The estimated hazard ratios for non-inferiority comparisons between 'evidence-based compression' and two-layer compression bandages were 1.01 (95% CI 0.79 to 1.28) and 1.16 (95% CI 0.86 to 1.58) for the intention-to-treat and per-protocol analyses respectively. The VenUS 6 team's interpretation of the findings was that "time to healing was slower in the compression wrap group compared with both the evidence-based compression group and the two-layer compression bandage group". The EAG agreed that the findings showed that compression wraps were less clinically effective than 'evidence-based compression' (i.e. four-layer compression bandages and two-layer hosiery). The EAG considered that the comparison between compression wraps and two-layer compression bandages did not show clear evidence that compression wraps were less clinically effective than two-layer compression bandages as statistical significance was not reached.

3. VENUS 6 NETWORK META-ANALYSIS AND ECONOMIC MODEL

MANUSCRIPT

Information about the VenUS 6 network meta-analysis (NMA) is summarised in the EAG report (Section 5.5.1). The VenUS 6 base case NMA combined two-layer compression hosiery and four-layer compression bandaging as a single node called 'evidence-based compression'. VenUS 6 justified this based on the findings of VenUS-IV³ which did not find evidence of a statistically significant difference between these two treatments, as well as clinical expert advice. A scenario analysis relaxing this assumption was provided to the EAG on request but is not included in the manuscript as it does not reflect the VenUS 6 preferred assumptions. Evidence from the NMA was identified from an updated Cochrane review⁴ as well as from the VenUS-6 trial. The NMA was restricted to RCTs and evaluated 'any type of compression bandage system or compression stockings' for venous leg ulcers. The primary outcome measure for the NMA was the HR of time to ulcer healing, comparing alternative compression systems. Methodological considerations related to the NMA were discussed in the EAG report (Section 5.5.1).

The VenUS 6 NMA included 21 RCTs with a total of 2,934 participants. Four trials (19%) were assessed as having a low risk of bias and five trials (24%) were assessed as having a moderate risk of bias. The others were assessed as having a high risk of bias. There were no statistically significant differences between arms. The VenUS 6 manuscript states that two-layer bandaging and short-stretch bandaging were "generally as effective as" 'evidence-based compression' (i.e. four-layer compression bandaging and two-layer compression hosiery) in terms of time-to-healing (HR versus 'evidence-based compression') 0.972 (0.851 to 1.107) for short-stretch bandaging, 1.044 (0.859 to 1.255) for two-layer compression bandaging. The EAG agreed with this assessment. The VenUS 6 manuscript also states that 'use of compression wraps had a lower likelihood of being effective than evidence-based compression'. As the HR for compression wraps was 0.927 (0.745 to 1.136), showing no evidence of a statistically significantly worse outcome on compression wraps compared to 'evidence-based compression', the EAG preferred an interpretation that there is no clear evidence that compression wraps were less clinically effective than 'evidence-based compression'.

A decision-analytic approach was used, updating the VenUS-IV model,³ to model the cost-effectiveness of different treatment approaches for venous leg ulcers. A summary of the VenUS 6 modelling approach and an initial comparison between the VenUS 6 and EAG modelling approaches and results is provided in the EAG report (Section 9.3). Briefly, the economic analysis extrapolated the results of the trial and relative treatment effects (from the NMA) to a life-time horizon. The VenUS 6 decision model used the VenUS 6 base case NMA, i.e. assuming equivalence between four-layer compression bandaging and two-layer compression hosiery. A Markov model structure was used, which is consistent with the EAG's approach. Key differences in the EAG and VenUS 6 study team's models were in the time horizon, source of resource use and health state utilities and (most importantly) relaxing the assumption of equivalence between compression hosiery and four-layer compression bandages. Both models implicitly accounted for treatment switching in outcomes by virtue of the construction of the survival functions (time to healing), based on intention to treat. The EAG's analysis did not account for treatment switching on costs. It is unclear whether the Venus 6 study team's analysis did so as disaggregated costs are not reported.

The VenUS 6 NMA and economic model manuscript notes that there are "relatively small differences in total costs and total QALYs" across all treatment options. This is demonstrated in Table 1 below. The VenUS 6 decision model shows that 'evidence-based compression' dominates short-stretch bandaging and compression wraps and that two-layer compression bandaging is not cost-effective versus 'evidence-based compression' (ICER = £159,614). As such, the VenUS 6 decision model supports 'evidence-based compression', i.e. four-layer compression bandaging or two-layer compression hosiery.

Table 1. VenUS 6 model cost effectiveness results

Treatment	EBC	SSB	2LB	CW
Total costs £, mean (95% CI)	2,634 (1,099 to 5,847)	3,024 (1,252 to 6,418)	2,979 (1,253 to 6,392)	2,983 (1,223 to 6,495)
Total QALYs, mean (95% CI)	6.53 (6.16 to 6.89)	6.52 (6.16 to 6.89)	6.53 (6.17 to 6.89)	6.52 (6.16 to 6.88)
Incremental costs £, mean (95% CI)	Reference treatment	390 (41 to 985)	345 (-102 to 1,127)	348 (-133 to 1,118)
Incremental QALYs,	Reference treatment	-0.0015 (-0.011 to 0.0064)	0.0022 (-0.0085 to 0.01)	-0.0044 (-0.0207 to 0.0079)

mean (95% CI)				
ICER (£/QALY gained)	Reference treatment	Dominated b	159,614	Dominated b
NMB ^a , mean (95% CI)	127,870 (119,772 to 135,515)	127,450 (119,146 to 135,208)	127,568 (119,587 to 135,251)	127,434 (119,242 to 135,242)
Incremental NMB ^c , mean (95% CI)	Reference treatment	-419 (-1,186 to 68)	-302 (-1,221 to 347)	-436 (-1,602 to 274)

a at a cost-effectiveness threshold of £20,000/QALY gained. A positive incremental net monetary benefit implies that the treatment is cost-effective; b Dominated: the treatment is more expensive and offers less health benefits than the reference treatment; c Incremental NMB indicates the differences in NMB of comparators against the reference treatment; positive values indicate that the treatment is cost-effective and negative values the opposite.

Abbreviations: 2LB, Two-layer compression bandage systems; CI, confidence interval; CW, Compression wraps; EBC, Evidence-based compression; ICER, incremental cost-effectiveness ratio; NMB, net monetary benefits; QALYs, quality-adjusted life years; SSB, Short-stretch bandage

4. DISCUSSION

The EAG considered VenUS 6 to be a well-conducted clinical trial at low risk of bias that offers valuable insight into the relative effectiveness of different forms of strong compression for venous leg ulcers. The EAG preferred allowing each treatment option to vary independently. This view was based on alignment with the NICE scope for this appraisal, but also a broader preference from the EAG to consider each technology separately. VenUS 6 preferred to use the concept of ‘evidence-based compression’ to cover four-layer compression bandages and two-layer compression hosiery rather than letting them vary independently. This view was based on the results of the VenUS-IV³ trial and how the treatments are used in practice. These different preferences fed through into differences in the preferred NMAs between VenUS 6 and the EAG, and ultimately different decision models. The VenUS 6 and EAG decision models come to different conclusions: the VenUS 6 study team conclude EBC (a blend of two-layer hosiery and four-layer compression bandages) is the most cost-effective option, whilst the EAG’s assessment is that compression wraps are more likely to be cost-effective. This arises because of differences in the clinical inputs used in the decision model, i.e. the use of different scenarios from the NMA. The VenUS 6 NMA assumes four-layer compression bandaging and two-layer compression hosiery to be identically effective as ‘evidence-based compression’. In contrast, the EAG preferred the scenario analysis supplied by the VenUS 6 team that relaxed this assumption.

This led to differences in the relative strength of the links within the NMAs: the VenUS 6 approach avoids having to rely on a link in the network based on two studies that have been assessed at high risk of bias. These studies connect the four-layer compression bandages and two-layer compression hosiery nodes in the NMA, so assuming these two treatment options are equal as ‘evidence-based compression’ means that the connection between these nodes is not required. One potential limitation of the EAG NMA, although it is better aligned with the NICE decision problem for this appraisal, is that the EAG NMA results for two-layer compression bandages and compression wraps are based on smaller and lower-quality studies in the network. This reflects the evidence available to inform the comparison between these technologies unless an assumption of equal efficacy between them is made. However, the VenUS 6 NMA does not allow for the possibility that four-layer compression bandaging and two-layer compression hosiery have different effectiveness. The EAG preference to allow four-layer compression bandages and two-layer compression hosiery to vary independently as separate

nodes in the NMA was better aligned with the NICE decision problem for this topic, where the four treatments to be compared were four-layer compression bandages, two-layer compression bandages, two-layer compression hosiery, and compression wraps.

Therefore, VenUS 6 and the EAG used different NMAs based on different network structures to inform their respective decision models. Neither NMA showed any statistically significant differences in clinical effectiveness between treatment options. Therefore, the EAG considered that the available evidence supported clinical equivalence between treatment options. Decision models are generally interpreted on the basis of estimated means / point values rather than the rules of statistical hypothesis testing. Therefore, small differences that are not statistically significant can have a significant impact on the ICER and ultimately drive the conclusions of the decision model. This is especially the case when total costs and QALYs are very similar across arms. This is what we observe here: as total costs and QALYs are very similar, the ICER is driven by small differences between treatments in terms of clinical effectiveness. As such, the choice of the VenUS 6 NMA or the EAG NMA is what determines the results of the decision model.

While neither NMA shows any statistically significant differences between treatment options, the point estimates were in the opposite direction: the EAG preferred NMA (VenUS 6 scenario NMA) showed a small non-statistically significant difference in favour of compression wraps (0.93 [0.74, 1.14], Table 8 EAG report), whereas the VenUS 6 NMA showed a small non-statistically significant difference in the other direction (1.12 [0.73, 1.64], Table 9, EAG report), i.e. compression wraps being less effective. The consequence of these differences in NMA results is that the EAG decision model concluded that compression wraps had the highest probability of being cost effective, whereas the VenUS 6 decision model concluded that 'evidence-based compression' i.e. four-layer compression bandaging or two-layer compression hosiery dominates compression wraps.

5. CONCLUSION

- The differences in the Venus 6 study team's results and those of the EAG are driven by the hazard ratio for compression wraps switching to greater than and less than one in each NMA scenario.
- The absolute differences in cost and outcomes between each of the four compression product types are small, thus the consequence of decision error is relatively low.
- The EAG's analysis suggested 2LCB and 4LCB are more expensive than compression wraps or compression hosiery, but all modalities accrued very similar outcomes. The EAG's analysis thus broadly favours compression wraps and compression hosiery.
- The Venus 6 study team's cost effectiveness analysis suggested 2LCB and compression wraps are more expensive than compression hosiery and 4LCB ('EBC'), but all modalities accrued very similar outcomes. The Venus 6 study team's analysis thus broadly favours compression hosiery and 4LCB.
- Both analyses support two layer compression hosiery as a cost-effective option. Combining compression hosiery and 4LCB into a single 'EBC' arm masks any cost differences between the two.
- Drawing on both the EAG's and Venus 6 study team's analyses, the EAG's view is that compression hosiery is likely to represent the best value for money treatment, whilst 2LCB and 4LCB are likely more expensive for very little added benefit. The position of compression wraps is uncertain, driven by uncertainty in both cost (and to a lesser extent) effectiveness: the EAG estimated they were less costly than 2LCB, whilst the Venus 6 study estimated them to be as costly.

6. REFERENCES

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