NICE advice

Coban 2 for venous leg ulcers

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Coban 2 compression bandage for venous leg ulcers.
- The **innovative aspect** is that it is thinner than 4-layer bandages. This aims to improve mobility and convenience.
- The intended **place in therapy** would be as an alternative to current compression bandages in selected people with venous leg ulcers.
- The **main points from the evidence** summarised in this briefing are from 3 studies (2 in UK, 1 in Italy; comprising 2 randomised controlled trials [RCTs] and 1 observational study) including a total of 1,456 adults with venous leg ulcers. The evidence is limited in quantity and quality. One randomised study showed that Coban 2 slipped significantly less than 4-layer bandages. The studies showed Coban 2 is as effective for wound healing as other compression bandages.
- **Key uncertainties** around the evidence or technology are that there are no studies showing better wound healing than 4-layer bandages.
- The **cost** of Coban 2 is £8.24 per unit (excluding VAT). The **resource impact** would likely be similar to standard care (£4 to £15 depending on size of bandage).

The technology

Coban 2 compression bandage system (3M) is a multilayer compression bandage for treating venous leg ulcers. It has 2 layers: a polyurethane foam inner layer for padding; and an outer layer of

elastic and short-stretch fibres for therapeutic compression. It is suitable for people with an ankle brachial pressure index (ABPI) of 0.8 or higher. Coban 2 Lite exerts less pressure and is suitable for people with an ABPI higher than 0.5. Coban 2 Lite can be used in people who can't have or don't want full compression. The layers have a cohesive backing that fuses them together into a stiff sleeve, which is designed to reduce slipping. It is latex free and may be worn for up to 7 days.

Innovations

Coban 2 is thinner than standard 4-layer bandages, which is designed to allow patients to have better mobility and to allow a greater choice of shoes to be worn. In addition, the proprietary materials are designed to minimise slipping between the dressing layers.

Current care pathway

The NICE clinical knowledge summary on venous leg ulcers recommends that a professional with expertise in wound management is involved in the person's care (such as a district nurse or tissue viability nurse). Compression therapy should be given to all people with non-infected venous leg ulcers with an ABPI of 0.8 or higher. When compression therapy is used, it should be tailored to the person. This includes a considering that a 2-layer bandage is, compared to a 3- or 4-layer bandage, more practical for people who are mobile.

Population, setting and intended user

Most people with venous leg ulcers are treated in the community. Coban 2 would be applied by practice or community nurses, with support from tissue viability specialists, and would be used instead of 4-layer bandages. Healthcare providers already trained in multilayer compression bandaging would need a short training session but no organisational changes are likely to be needed.

Costs

Technology costs

Table 1 Technology costs and costs of standard care

Description	Cost	Additional information

Coban 2	£8.24	Bandages must be replaced weekly by a trained healthcare professional.
Coban 2 Lite	£8.24	
Profore	Ankle circumference <18 cm, £13.38; 18 cm to 25 cm, £9.54; 25 cm to 30 cm, £10.19; above 30 cm, £15.11.	
Urgo K-Four 4-layer compression bandage	Ankle circumference <18 cm, £6.73; 18 cm to 25 cm, £6.44; 25 cm to 30 cm, £6.44; above 30 cm, £8.87; reduced compression 18 cm and above, £4.21.	

Resource consequences

Several company-sponsored studies on the resource consequences of Coban 2 were identified, which suggest that is cost saving compared with 2-layer compression bandages such as UrgoKTwo and Profore. The largest and most relevant resource study, Guest et al. (2017) showed that Coban 2 was cheapest in terms of community nurse visits, analgesics and anti-infectives compared with UrgoKTwo and Profore over 6 months in the NHS (data from THIN database). This study also recorded that time to healing was significantly less for Coban 2 than for UrgoKtwo and Profore and that health-related quality of life was highest in the Coban 2 group at 0.413 quality-adjusted life years (QALY) compared with 0.404 for Ktwo and 0.396 for Profore. This study was funded by a research grant from the company, 3M. Up to 23% people switched compression therapy treatments during the study period and this was not accounted for in the analyses. Participants were not blinded or randomised.

The specialist commentators stated that the main drivers of costs for compression bandaging were staff training and staff time.

Coban 2 kits come in 1 size, intended to fit all leg sizes and is latex free. Coban 2 would represent a small additional costs compared with standard 4-layer dressing which would likely be offset if it promoted better compliance with compression bandaging.

The company has stated that Coban 2 is in use in 15 NHS organisations.

Regulatory information

Coban 2 was CE marked as a class I medical device in 2007.

The FDA database of adverse events (MAUDE) has 5 reports for adverse events associated with Coban 2 since January 2000. Two of these were in people with venous leg ulcers:

- A person with deep vein thrombosis with venous stasis ulcer. After treatment with Coban 2 there was ulceration on the tendon, needing surgery.
- A person with a venous leg ulcer and a non-traumatic injury on the lower left leg. After treatment with Coban 2, a necrotic lesion was noted measuring 4 cm x 3.5 cm with a depth of 0.3 cm. The lesion was over the left ankle and there was an exposed tendon.

No adverse events were found following a search of the Medicines and Healthcare products Regulatory Agency website. However, a Coban 2 Field Safety Notice from 2016 addresses an error in the print on the Coban 2 packaging.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Three studies, including data from a total of 856 people with venous leg ulcers, are summarised in this briefing.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The studies in the table include 2 randomised comparisons and 1 retrospective observational comparative study using routinely collected NHS data. In 1 RCT (Moffatt et al. 2008), there was no significant difference in wound healing between Coban 2 and Profore, but Coban 2 performed better in slipping, health-related quality of life and patient preference. The second RCT (Mosti et al. 2011) was done in Italy and compares Coban 2 with the Unna boot, which is not routinely used in the NHS. Coban 2 slipped more but there were no significant differences in wound healing, pain or patient comfort. The observational study (Guest et al. 2015) uses data collected in the NHS and shows that Coban 2 performs best for ulcer healing and health-related quality of life compared with Profore and UrgoKTwo. Patient characteristics were not reported.

All 3 studies included in the briefing were funded by the company and so may be prone to bias. Only 1 study followed people until complete wound healing; the other 2 studies followed people for 8 weeks or 6 months. With the right treatment, venous leg ulcers tend to heal within 3 to 4 months, meaning that a follow-up period of less than 6 months is likely too short.

Table 2 Summary of selected studies

Moffatt et al. (2008)	
Study size, design and location	81 people with venous leg ulcers were enrolled in an 8-week, randomised, open-label, crossover clinical trial. Location: 10 centres in UK.
Intervention and comparator(s)	Coban 2 and Profore 4-layer compression bandage.
Key outcomes	Primary outcome: Mean bandage slip at each dressing change: 2.48 cm for Coban 2 and 4.17 cm for Profore. Secondary outcome: No significant differences in wound healing between the bandages. Significantly higher HRQoL scores (physical symptoms and daily living) for Coban 2 compared with Profore. Patient preference was recorded as: 72% Coban 2; 22% Profore; and 6% no preference.

Strengths and limitations	This study was designed to collect outcomes relevant to patient experience, for example: bandage slip and associated HRQoL. The study did not collect data on complete wound healing. Data are collected from an NHS setting. 3M provided financial support for this study.
Mosti et al. (2011)	
Study size, design and location	100 people with venous leg ulcers were enrolled in a prospective, multicentre RCT. Follow-up appointments weekly for 3 months, followed by monthly appointments until full wound closure. Location: Italy.
Intervention and comparator(s)	Coban 2 (50 people) and Unna boot (50 people).
Key outcomes	Primary outcome: No significant difference in wound healing, pain or exudate. Secondary outcome: No significant difference in patient comfort between the 2 devices. Bandage slip and skin scaling happened significantly more often with Coban 2 than with Unna boot (11 versus 5 for slip and 21 versus 7 for skin scaling). The authors reported that Coban 2 is easier to apply and remove than Unna boot.
Strengths and limitations	The Unna boot is not routinely used in the UK. The authors describe a 'modified Unna boot' but do not give detail on the modifications. The patient population in the study was 76% female. 3M provided Coban 2 free of charge.
Guest et al. (2015)	
Study size, design and location	The case records (the Health Improvement Network database) of 675 people with venous leg ulcers were used to inform a retrospective analysis. Location: UK.
Intervention and comparator(s)	Coban 2 (250 people), Ktwo 2-layer compression bandage (250 people) and Profore 4-layer compression bandage (175 people).

Key outcomes	During the 6-month study period, 51% of venous leg ulcers treated with Coban 2 had healed compared with 40% for Ktwo and 28% for Profore. HRQoL was highest in the Coban-2 group at 0.374 QALY compared with 0.368 QALY for Ktwo and 0.353 QALY for Profore.
Strengths and limitations	This study was funded by a research grant from the company. Data are collected from the NHS. The THIN data cut off at 6 months after first treatment with compression. The authors do not report patient characteristics but stated that the 'average patient' had been considered in the analyses.
Abbreviations: HRQoL, health-related quality of life; QALY, quality-adjusted life years.	

Recent and ongoing studies

The following ongoing trials were identified:

Cost Evaluation of Venous Leg Ulcers Management, NCT02728986; location: France; study completion: December 2017; sponsor: 3M.

Randomized Clinical Trial (RCT) to Compare the Efficacy of Coban 2 Versus SSB in the Treatment of Venous Leg Ulcers, NCT00558662; location: UK Belgium, Germany and Netherlands; study completion: November 2011; no results posted; sponsor: 3M.

Specialist commentator comments

Comments on this technology were invited from 4 clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two specialists reported using Coban 2 (and other bandages) routinely; another specialist had not used Coban 2 but was familiar with the technology and other compression bandage systems; the fourth specialist had used Coban 2 but does not use it currently.

Level of innovation

All 4 specialists stated that Coban 2 is a minor variation of other short-stretch compression bandages. Two specialists noted that the foam layer was unique to Coban 2. One stated that the layers do not slip over each other, improving comfort for the wearer. One specialist noted that Coban 2 is best suited to ulcers with relatively little exudate because it only has 2 layers; more

absorbent 4-layer bandages are better for ulcers with large amounts of exudate. One specialist stated that other bandages are not materially different to Coban 2. One specialist stated that 2 layers of bandaging is easier to apply than 4. They also noted that as Coban 2 can be adjusted as the person's ankle circumference decreases, rather than having to order a new size.

Potential patient impact

One specialist stated that Coban 2 could offer greater comfort for some people and therefore improve compliance to compression therapy. One specialist noted that people wearing Coban 2 will feel that their bandages are the correct size. Three specialists state that this is particularly relevant for people leading an active lifestyle and those who work. These specialists stated that Coban 2 was resistant to slipping and could be worn with a greater choice of shoes. The specialist also stated that Coban 2 might minimise time off work for people needing treatment for venous leg ulcers. This is because they might feel more comfortable and are able to wear their usual shoes. One specialist stated that using Coban 2 could lead to improved ulcer healing and oedema reduction.

Potential system impact

One specialist stated that Coban 2 could reduce clinic and hospital visits because of reduced oedema, exudate and bandage slip and improved compliance. This specialist also noted the potential cost savings from reducing the frequency of bandage application to once a week. They said that other bandages may need to be changed more often because of slipping. The specialist also noted that there is no need for prescription shoes to be worn with Coban 2. Two commentators stated that Coban 2 offered the same system benefits as other multilayer compression bandages. One specialist stated that hospital visits are unlikely to be reduced unless Coban 2 led to faster healing times.

Three specialists noted that there would be little or no change needed to the care pathway or to how services are delivered. The specialists advised that training is straightforward for staff already trained in compression bandaging. One specialist noted that any change in practice would need to be supported by new training and competency frameworks for tissue viability nurses delivering training for leg ulcer management in the community.

Two specialists stated that the cost of using Coban 2 is likely to be the same as any other compression bandage. One specialist stated that Coban 2 is likely to be more expensive than 4-layer bandages (Profore) because of the higher purchase price.

General comments

Two experts noted that it is not possible to have a one-size-fits-all bandage that will accommodate all leg sizes. One specialist noted that much of the evidence for Coban 2 is funded by the company and that an independent trial comparing Coban 2 to 4-layer bandaging would be useful.

Specialist commentators

The following clinicians contributed to this briefing:

- Mr Stephen Blair, consultant vascular surgeon, Arrowe Park Hospital. Did not declare any conflicts.
- Ms Jane Todhunter, vascular nurse practitioner, North Cumbria University Hospitals. Did not declare any conflicts.
- Prof Charles McCollum, professor of surgery, University of Manchester. Has a financial interest in a company that makes compression stockings.
- Ms Joanne Beresford, wounds clinical nurse specialist, Leeds Community Healthcare NHS Trust. Did not declare any conflicts.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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