NICE National Institute for Health and Care Excellence

NICE guidance

# Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers

Medical technologies guidance

Published: 12 November 2014
nice.org.uk/guidance/mtg20

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# Contents



© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. The medical technology guidance on 'Parafricta Bootees and Undergarments' recommends further research. This recommendation is not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1.1 Parafricta Bootees and Undergarments show potential to reduce the development and progression of skin damage caused by friction and shear in people with, or at risk of, pressure ulcers. However, more evidence for their effectiveness in clinical practice is needed to support the case for routine adoption of Parafricta Bootees and Undergarments in the NHS.

1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of using Parafricta Bootees and Undergarments. This should take the form of comparative research against standard care, preferably carried out in a hospital. The research should include development of criteria to recognise people who would most benefit from the technology in both hospitals and community care. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will update this guidance if and when substantive new evidence becomes available.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 2 The technology

## *Description of the technology*

2.1 Parafricta Bootees and Undergarments (APA Parafricta) are intended to reduce the potential for both the development and the progression of skin damage caused by friction and shear in people who have, or are at risk of developing, pressure ulcers, and in people with frail skin or those who have medical conditions in which skin frailty is a primary factor. Bootees provide protection for the heel and ankle, and Undergarments provide protection for the sacrum, buttocks and hips. The items are made from proprietary Parafricta fabric which is designed to reduce the shear stress and friction associated with movement. It has a friction coefficient value of 0.2, whereas most textiles typically range from 0.3 to 0.7. Parafricta fabric has no stiction, which is the additional force needed to overcome skin sticking to a surface before sliding. Because of this, it reduces the 'jerk' effect on skin when movement occurs. The lower the friction and stiction, the less likely it is that shear forces will develop and break the skin down, thereby reducing the risk of pressure ulcers. This mechanism of action is different from current methods of pressure ulcer management or prevention, which aim to manage or prevent pressure ulcers by reducing or redistributing pressure.

2.2 Parafricta fabric is used to protect the skin in areas most at risk. Both Parafricta Bootees and Undergarments have non-slip areas to help patient positioning, and Velcro fastenings for easy application and removal. The positioning of the Velcro fasteners and the garments' flat seams are designed to minimise skin creasing or damage. The Bootee is supplied singly and is available in a range of adult sizes (starting from an adult size 2). They come in 2 types – with slip-on or Velcro fasteners – and have non-slip soles. The Undergarment is available in several sizes as a slip-on garment or with Velcro fasteners, and as briefs or boxer shorts. Parafricta fabric is described as breathable but durable. The products are reusable after washing in accordance with garments for NHS use.

2.3 The cost of each Parafricta Bootee stated in the sponsor's submission is £35.14 (excluding VAT). The cost of the Parafricta Undergarment stated in the sponsor's submission is also £35.14 (excluding VAT). Parafricta garments are prescribable on a standard FP10 prescription.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

2.4 The sponsor's claimed patient and healthcare benefits for Parafricta Bootees and Undergarments are as follows:

- A reduction in pressure ulcer incidence and severity in people who are at high risk of pressure ulcers following assessment, thereby reducing or avoiding adverse impact on quality of life, pain, discomfort, hospital length of stay, morbidity and mortality.
- Protection of susceptible skin in people in whom a repetitive, rubbing motion – due to an underlying neurological or other medical condition – can break down the skin.
- Ease of use for patients and carers, combined with a familiarity with the type of products in older people or those with cognitive impairment, may lead to greater compliance with pressure ulcer preventative measures.
- The products can be used in the home or in community care or hospitals, enabling the patient to easily transition between these settings.
- The ease of use and practicality of Parafricta garments imply that the technology may be implemented easily in the community, and could be used as a long-term care strategy to improve people's quality of life.
- Prevention of pressure ulcer formation and reduced pressure ulcer incidence would shorten stays in hospital and may allow people to be transferred to lower cost community care. Hospital-acquired pressure ulcers result in lengthened hospital stays and increased complications.
- Reduction in NHS costs including but not limited to:
  - quicker return of people to the community or community long-term care
  - reduced pressure ulcer incidence resulting in lower costs of nursing care, dressings and rehabilitation
  - the reusable nature of the garments.

## *Current management*

2.5 Current options to reduce breakdown of frail skin and to prevent and manage pressure ulcers focus on the reduction or redistribution of pressure. They include: dynamic or static high-specification pressure-relieving or pressure-redistributing beds, mattresses, overlays and cushions; and sheepskin

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

or pressure-relieving bootees or silicone gel pads (numerous products, shapes and sizes are available).

2.6 NICE's guideline on pressure ulcers states that there is overlap between ulcers caused mainly by moisture and those caused by shear stresses or friction rather than pressure alone. This can cause some confusion in classification. In reality, however, pressure, shear, friction and moisture may all contribute in varying degrees to the development of an ulcer. The guideline recommends that when a person presents with or is at increased risk of developing a pressure ulcer, risk should be assessed and documented and then reassessed regularly.

2.7 NICE's guideline on pressure ulcers recommends that risk assessment should be followed by consideration of mobilising, positioning and repositioning interventions to prevent or minimise skin damage. When indicated, the recommended minimum provision is a high-specification foam pressure-relieving mattress or high-specification foam mattress with an alternating pressure overlay, or a sophisticated continuous low pressure system. Any ulcer should be closely observed for deterioration.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 3 Clinical evidence

## *Summary of clinical evidence*

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes for Parafricta Bootees and Undergarments presented in the decision problem were:

- incidence and severity of pressure ulcers or skin breakdown
- length of hospital stay
- time to healing for those with an existing pressure ulcer
- compliance with pressure ulcer management
- the person's comfort (including ability to move and self-reposition in bed)
- quality of life
- device-related adverse events.

3.3 The clinical evidence for Parafricta Bootees and Undergarments presented by the sponsor was 4 published multiple-patient case-series reports, 3 of which were peer-reviewed papers (1 with historical controls) and 1 poster. These were Hampton et al. (2009), Loehne (2013; poster), Smith and Ingram (2010; with historical controls) and Stephen-Haynes and Callaghan (2011). The sponsor also identified 3 single case studies but these were not presented. Independent searches by the External Assessment Centre found no additional relevant studies. Data from an unpublished audit (Gleeson 2014) were sent to the External Assessment Centre by the sponsor during the evaluation.

### Multiple-patient case series: peer-reviewed papers

3.4 A case series of 25 nursing home residents by Hampton et al. (2009) evaluated whether using a Parafricta Bootee or Undergarment could reduce oedema and inflammation associated with pressure ulcers. All residents had restricted mobility and each had redness and a 'boggy' feel to the tissues, either over the sacrum or 1 or 2 heels. A total of 28 pressure ulcers of grade 1 or above were

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

analysed, all of which were related to friction or shear. Ten people used a Parafricta Bootee on the right heel (the left heel [control] without the Bootee was used as a comparator) and 18 used a Parafricta Undergarment ('normal' skin adjacent to the sacrum was used as a comparator). The degree of oedema and inflammation of the pressure ulcers was measured using 3 methods: high-frequency ultrasound scan data, colour photographs and tissue assessment by a tissue viability nurse. Statistical analysis of the high-frequency ultrasound data was conducted using the Kolmogorov–Smirnov 2-sample test. For this analysis, the skin profile of each heel (treated and control) was compared with a 'normal' heel profile (a standard heel with no pressure ulcer or redness). At the start of the study, results showed that both the treated heel ($p<0.001$) and the control heel ($p<0.001$) were statistically significantly different from the normal heel. At the end of 4 weeks, the difference between the treated heel and the 'normal' heel had reduced ($p=0.2$), whereas the difference between the control heel and the 'normal' heel was still statistically significant ($p<0.001$). Analysis of the treated heel results at week 0 compared with week 4 showed an improvement with a statistically significant difference ($p<0.001$). Based on these results, the authors concluded that the heel treated with a Parafricta Bootee became more similar to the 'normal' heel, and that Parafricta garments were effective in reducing oedema. The tissue viability nurse assessment found that bogginess and redness were reduced in the treated heels of all 10 residents but there was no change in the control heels. Results from the analysis of the high-frequency ultrasound data for the sacral area showed a statistically significant difference between baseline and week 4 ($p=0.006$). Bogginess and redness were reduced in all 18 residents treated with a Parafricta Undergarment. The colour photographs for both the heels and the sacral areas were not considered clear enough by the researchers to validate the results. The ultrasound data were deemed to be more objective and reliable than either the colour photographs or the visual assessment.

3.5 The case series by Loehne (2013; poster) evaluated the use of Parafricta Bootees to prevent pressure ulcers in nursing home residents who were at risk of developing heel pressure ulcers as a result of friction and shear. Although the poster did not report how many residents were involved, the sponsor submission stated that the study included 6 residents and the intervention was a standard pressure-reducing surface plus a Parafricta Bootee. After 30 days, none of the residents had developed a pressure ulcer or had any healed ulcers

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

recurring. This included 1 person who had had a recurrent pressure ulcer for 2 years.

3.6 Smith and Ingram (2010) investigated the effectiveness of Parafricta garments in reducing the incidence and prevalence of pressure ulcers in hospital. The study incidence data were collected from 2 medical wards and 1 orthopaedic ward over 6 consecutive months. The first 3 months provided the data for group 1 (n=204) and the next 3 months were used for group 2 (n=165). People in both groups had identical care using the hospital's standard pressure ulcer prevention protocol, except that those in group 2 were also given a Parafricta Bootee or Undergarment. It was not clear how many had a Bootee or an Undergarment or both. Analysis of Waterlow scores suggested that they did not differ between the 2 groups. The authors reported the results as percentage differences in incidence of pressure ulcers between the groups. For additional ease of interpretation, the External Assessment Centre recalculated the results as relative risks. The results showed that at-risk people who were admitted to hospital without a pressure ulcer were more likely to develop a pressure ulcer in the no Parafricta group than in the Parafricta group (relative risk [RR] 1.64, 95% confidence interval [CI] 1.05 to 2.59). For at-risk people admitted without a pressure ulcer who then developed one, those in the no Parafricta group were more likely to have an ulcer that deteriorated or did not improve compared with those in the Parafricta group (RR 2.53, 95% CI 1.16 to 5.52). A similar result was found for people who were admitted with an existing pressure ulcer: risk of deterioration was more likely in the no Parafricta group than in the Parafricta group (RR 4.90, 95% CI 1.75 to 13.75). There was no statistically significant difference between the groups in the risk of developing an additional ulcer in people who were admitted with one (RR 1.55, 95% CI 0.87 to 2.75). The Smith and Ingram (2010) study reported median lengths of stay. The External Assessment Centre obtained the study data from the sponsor and reanalysed it to calculate mean lengths of stay for each group as a more appropriate parameter for use in the economic model. The average length of stay was calculated by weighting the length of stay in each treatment group by the proportion of people in the group. Results showed a weighted mean length of stay of 20.31 days for the no Parafricta group and 16.27 days for the Parafricta group, a statistically significant difference of 4.05 days (p=0.019). The External Assessment Centre also used the limited information on confounding factors to estimate adjusted length of stay values, which took into account reported baseline characteristics between the groups. Results showed a weighted mean

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

length of stay of 14.94 days for the no Parafricta group and 12.47 days for the Parafricta group, a difference of 2.47 days. No demographic characteristics were reported for either group.

3.7 Stephen-Haynes and Callaghan (2011) described a case series of 25 nursing home residents who used Parafricta Bootees and Undergarments in addition to the standard approach for ulcer prevention and management as outlined in NICE's guideline on pressure ulcers. At the start of the study, 20 residents had an existing pressure ulcer of category 2 or below and 5 had intact skin. Those with intact skin were considered at risk of developing a pressure ulcer through friction due to repetitive movements caused by their medical condition. The outcomes that were considered included skin improvement, ease of use, garment retention and patient comfort. No information about the timescale of the study was provided. There was skin improvement in 76% (n=19) of residents, whereas 24% (n=6) remained the same. Clinicians found the garments very easy to use for most people (64%, n=16), and 88% (n=22) of clinicians stated that Parafricta garments had a positive impact on clinical outcomes. All residents in the study found the garment comfortable (24%, n=6) or very comfortable (76%, n=19). Almost half (48%; n=12) of clinicians reported that it was very easy to keep the garments in place, and 16% (n=4) did not find it easy. This was an uncontrolled study so it was difficult to tell whether any improvement in pressure ulceration or skin improvement was temporary or prolonged, or even whether any improvement was because of Parafricta garments.

### *Summary of results from the unpublished audit*

3.8 The unpublished clinical audit by Gleeson (2014) evaluated the use of Parafricta Bootees in people at high risk of pressure ulcers on 6 hospital wards in the St. Helen's and Knowsley Teaching Hospitals NHS trust over a 12-month period (January to December 2012). The author reported a 32% reduction in hospital-acquired grade 2 pressure ulcers compared with the previous year. Other details were made available to the Committee on an academic-in-confidence basis and the author supplied additional academic-in-confidence information during the consultation, although details cannot be reported here. The External Assessment Centre considered it unclear how much of the reduction in pressure ulcers reported was because of the use

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

of Parafricta Bootees, and how much was caused by other pressure ulcer prevention initiatives taking place at the NHS trust.

## Adverse events

3.9 The sponsor found no adverse event reports relating to Parafricta garments. No alerts have been issued, and no information was found in a search of the Medicines and Healthcare Products Regulatory Agency website.

## Committee considerations

3.10 The Committee noted that the clinical evidence base for Parafricta garments was 4 published multiple-patient case series and 1 unpublished audit. The Committee agreed with the External Assessment Centre's conclusions that there was a lack of good quality comparative evidence against standard care. The Committee recognised that there is often only limited evidence for products used in pressure ulcer prevention and management , but considered it possible to conduct comparative research of good quality to assess the clinical effectiveness of this technology.

3.11 The Committee accepted the External Assessment Centre's critique of the Smith and Ingram (2010) study and agreed that because of potential confounding factors, it is not clear that any change in the pressure ulcer incidence or severity was due to Parafricta garments. The Committee also agreed with the concerns raised by the External Assessment Centre about the unpublished Gleeson audit (2014), including the additional data submitted during consultation, and it was not convinced that the reduction in heel pressure ulcers documented in the audit was solely because of the Parafricta Bootees.

3.12 Based on the existing evidence base and expert advice, the Committee considered that Parafricta garments may indeed reduce pressure ulcer incidence and severity, and so provide potential benefits for patients. The Committee was aware that older people and those with frail skin are more susceptible to pressure ulcers as a result of friction or shear, and it considered that Parafricta garments may be particularly beneficial to these people. However, it judged that the case for routine adoption in the NHS could not currently be supported because there are too many uncertainties in the evidence base.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

3.13 The Committee wished to encourage comparative research in hospitals (for ease and speed of generating findings) to investigate the clinical effectiveness of Parafricta garments as an adjunct to standard care compared with standard care alone in reducing skin breakdown in people with or at risk of pressure ulcers. The study should be randomised and the assessors blinded to minimise bias in the results. The Committee specified that the research should focus on determining relative effectiveness compared with standard care when biases were carefully controlled for, and on developing criteria to identify patients for whom Parafricta garments are most likely to be effective.

3.14 The Committee recognised that there is great potential for the use of Parafricta garments in the community. It considered that they could be beneficial to patients with long-term conditions where pressure ulcers are a significant problem. However, it was advised of the significant challenges of conducting comparative research in the community. The Committee considered that the results obtained in hospitals could plausibly be generalisable , and advised that the need for the findings from a hospital setting to be generalised to community-based settings should be factored into the design of the research studies.

3.15 The Committee discussed outcomes of special importance to patients. It noted the results from the Stephen-Haynes and Callaghan (2011) case series which suggested that the garments were easy to use and that patients found them comfortable. Expert advice to the Committee was that the fastenings ensure the garments remain in place, and that they have proven popular with patients. No adverse events were identified as a result of their use. The Committee concluded that Parafricta Bootees and Undergarments are convenient, easy to use and well tolerated by patients, but considered that a record of patient experience would be useful to incorporate in future research studies.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 4 NHS considerations

## *System impact*

4.1 The Smith and Ingram (2010) study described in section 3.6 provides information on the incidence of pressure ulcers in an NHS hospital and on lengths of stay in hospital. During the selection of Parafricta Bootees and Undergarments, the Committee heard expert advice, based on this study and from 3 years' clinical use, that the routine management of washing the garments, educational support, and ensuring that appropriate decision-making protocols are used to identify the correct piece of equipment for at-risk patients were issues in the adoption of Parafricta garments.

4.2 Additional information on the impact of introducing Parafricta Bootees into another NHS hospital trust was provided by an audit at St. Helen's and Knowsley Teaching Hospitals NHS trust, described by Gleeson (2014; see section 3.8). Expert advisers who used Parafricta garments confirmed that locally developed pressure ulcer risk protocols were used to identify at-risk patients who could most benefit. An example of patients at risk of heel pressure ulcers as developed at St. Helen's and Knowsley Teaching hospital NHS Trust was presented to the Committee.

## Committee considerations

4.3 The Committee recognised that pressure ulcers are an important problem facing the NHS, both in hospitals and in the community.

4.4 The Committee was advised that recent progress in pressure ulcer care has focused on the use of pressure-reducing and pressure-redistributing devices, but that many patients remain at risk of a pressure ulcer caused by friction and shear. Experts who use Parafricta garments both in the community and in hospitals informed the Committee that they use locally developed protocols to identify people at high risk of developing pressure ulcers due to friction and shear. The Committee considered that there needs to be a way of clearly identifying patients who would benefit from the use of Parafricta Bootees and Undergarments and this should be considered in designing further research.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

4.5 The Committee heard from expert advisers about their experiences of using Parafricta garments in both hospital and community care. The experts described the positive effect of the technology on the prevention and management of pressure ulcers in certain patients, and good levels of acceptance among staff and patients.

4.6 A reduction in the length of stay was the key driver of the cost saving identified by the sponsor's model, but the Committee was unconvinced that this was the most reliable way to capture the benefits of Parafricta garments in a cost analysis. It considered that many patients who use Parafricta garments are likely to have comorbidities, which may indirectly influence the length of stay. Experts also advised the Committee that the pressure ulcers that are generally associated with longer hospital stays (grade 3 or 4) are relatively uncommon, and it is less likely that the development of more common grade 1 or 2 ulcers would prolong the length of hospital stay. The Committee concluded that collection of detailed resource use information on managing pressure ulcers in hospital was needed to inform a more appropriate cost analysis.

4.7 The Committee considered the logistics of providing Parafricta garments in hospital. It heard expert advice that the garments can be easily managed in this setting: patients are identified using a locally developed protocol before being issued with the garments from a central pool. Parafricta garments are cleaned in the same way as hospital mattresses and have proved to be very durable; in some cases, the garments have withstood more than 100 washes. A small number of Bootees are disposed of every month, based on an inspection by a clinician, usually because of worn non-slip soles or fraying at the seams. The Committee concluded that the estimates in the cost model of using each Parafricta garment only 6 times were likely to be conservative.

4.8 In response to questions about the possibility of cross-infection, the Committee heard expert advice based on experience of using Parafricta Bootees in an NHS hospital trust over 2 years. There had been no occurrences of infection attributable to the Bootee.

4.9 With regard to use in the community, the Committee was told by an expert about a locally defined protocol used to identify people at risk of developing a pressure ulcer caused by friction and shear in a community setting. Having received the garments on prescription, patients are responsible for their own

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

laundry. The Committee heard expert advice that people are happy to use these garments as a long-term care strategy to prevent and manage pressure ulcers. The Committee considered that if further research confirms the effectiveness of Parafricta garments in decreasing incidence and severity of pressure ulcers in hospital, the technology could have a positive effect on patients in the community.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 5 Cost considerations

## *Cost evidence*

### Published evidence

5.1 The sponsor identified 1 relevant study (Smith and Ingram, 2010). The External Assessment Centre agreed with its inclusion and did not identify any further studies. The study considered the cost effectiveness of Parafricta garments to see if any reduction in treatment costs outweighed the initial item cost. Costs were calculated for each treatment pathway, and it was estimated that Parafricta garments could save more than £63,000 per 100 at-risk people.

### Sponsor's cost model

5.2 The sponsor submitted a de novo cost analysis to assess potential cost savings when using Parafricta Bootees and Undergarments as an adjunct to current clinical care. Full details of all cost evidence and modelling considered by the Committee are available in the assessment report overview.

5.3 The sponsor submitted a base-case analysis for 1 hospital and 1 community setting. The population was people in the community or in hospital who:

- had a grade 1 or 2 pressure ulcer and were at risk of progressing to a grade 3 or 4 pressure ulcer
- did not have a pressure ulcer but were at risk of developing pressure ulcers caused by friction and shear
- had medical conditions in which frail skin is a primary factor and friction and shear could cause skin damage.

Separate analyses were conducted to reflect the garments' use in hospital or in the community. In hospital, potential cost savings were based on expected reductions in length of stay for people using Parafricta garments. In the community, potential cost savings were based on a reduced prevalence rate among those using Parafricta garments. No distinction was made between adults and children, or between the different pressure ulcer grades.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

5.4 The sponsor explored the uncertainty around the model parameters and the effect this had on the incremental cost using deterministic and probabilistic sensitivity analyses for both the hospital and community models.

### *Hospital model*

5.5 The sponsor's hospital model base case included several key assumptions. These were as follows:

- A time horizon of 1 year.
- Five potential pathways for at-risk people.
- The cost of treating people in each of the 5 pathways was calculated by applying the appropriate day costs to the relevant weighted length of stay.
- The only additional daily cost for people with a pressure ulcer compared with those without a pressure ulcer was an additional dressing cost of £0.74.
- Each person was allocated 6 garments.
- Each garment was washed on average twice over the person's length of stay.
- Each set of 6 garments was used by an average of 3 different people over the garments' lifetime.

5.6 The base-case results for the hospital model showed that using Parafricta garments saved £757 per at-risk person, based on costs of £5307 per at-risk person when the garments were not used and £4550 per at-risk person when they were. This was based on the cost of each Parafricta garment being £35.14 and an assumed laundry cost of £0.50 per wash, per garment. The weighted median length of stay was 13.7 days for the Parafricta group and 16.2 days for the no Parafricta group. The general hospital costs were £326.53 per day, comprising a bed day cost of £325, a £0.59 per-day mattress cost and a £0.74 general dressing cost. The additional dressing cost applicable to days with a pressure ulcer was £0.74.

5.7 The results from the sponsor's multi-way deterministic sensitivity analyses confirmed that the modelled cost savings were most sensitive to the weighted length of stay values used. In these results, Parafricta garments were cost saving in all cases, except when the median weighted length of stay without Parafricta

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

garments was 14.8 days and when the median weighted length of stay with Parafricta garments was 14.9 days. In the sensitivity analysis the cost savings were greatest when the median weighted length of stay without Parafricta garments was 17.7 days and when the median length of stay with Parafricta garments was 12.5 days.

### *Community model*

5.8 The sponsor's community model base case included several key assumptions. These were as follows:

- A time horizon of 1 year.
- For every person in the community with a pressure ulcer, there were 2 other at-risk people without a pressure ulcer.
- Costs in the community model were based solely on the annual cost of Parafricta garments and the costs associated with nurse visits.
- All people with pressure ulcers were assumed to need nurse visits.
- The difference between median length of stay when a pressure ulcer developed and time to develop a pressure ulcer was used as a proxy for pressure ulcer duration.
- The incidence per at-risk person and the pressure ulcer duration were used to calculate a point prevalence in Parafricta and no Parafricta groups.

5.9 The base-case results for the community model showed an annual cost saving of £3455 per person with a pressure ulcer. The base-case calculation for treating a person with a pressure ulcer in the community was £5900, based on 1.86 nurse visits a week at £61 per visit for 52 weeks. Treating a pressure ulcer with Parafricta garments was estimated at £2445, based on a prevalence ratio of 0.37 and an annual cost of £240 per person with a pressure ulcer.

5.10 Results from the deterministic sensitivity analysis always favoured the use of Parafricta garments and suggested cost savings of approximately £1500 to £4500. The lowest cost savings were obtained with a reduction in the effectiveness of Parafricta garments – by increasing the prevalence ratio to 0.685. Results from the probabilistic sensitivity analysis suggested that there is very little uncertainty and that Parafricta garments are always cost saving.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

## External Assessment Centre revisions to the hospital cost model

5.11 The External Assessment Centre did not consider that all of the assumptions in the sponsor's hospital cost model were optimum. The External Assessment Centre's revisions included a simplified structure based on 3 pathways, which avoided the small patient numbers in some pathways and also calculated mean lengths of stay adjusted with the limited baseline patient characteristics.

5.12 The External Assessment Centre also amended some of the costs in the model, the most noteworthy of which was the revision of the bed-day cost. A weighted cost using excess bed-day cost across a range of wards was used to obtain an estimate of £234 per day. The External Assessment Centre used a cost of £328 as an upper limit in the sensitivity analysis.

5.13 The revised hospital model base-case results suggested that use of Parafricta garments saved £595 per at-risk person. This was based on costs of £3556 per at-risk person if Parafricta garments are not used and £2960 per at-risk person if the garments are used. In a one-way sensitivity analysis with a bed day costing £328, the cost savings were increased to £863.

5.14 The External Assessment Centre also conducted a probabilistic sensitivity analysis which suggested that the use of Parafricta garments resulted in cost savings nearly 80% of the time. Most iterations suggested that Parafricta garments were cost saving, with maximum savings of about £6000 per at-risk person. However, there were some iterations in which the garments added costs, reflecting the uncertainty in length of stay data.

## External Assessment Centre revisions to the community cost model

5.15 The External Assessment Centre recalculated a prevalence ratio based on the adjusted mean length of stay data and obtained a value of 0.53. No other changes were made to the model.

5.16 The base-case results for the revised community model were estimated at £2510 per person with a pressure ulcer, based on an unchanged cost per person with a pressure ulcer of £5900 without Parafricta garments and £3390 with them. Deterministic sensitivity analysis varying the length of stay data based on lower and upper limits of 95% confidence intervals suggested that the cost savings could be between £2295 and £2799.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

## Committee considerations

5.17 The Committee considered that the hospital cost model structure was appropriate and that the sponsor had addressed some of the uncertainties in the cost model through sensitivity analyses. However, it noted that the model included very limited information on the resource implications of having a pressure ulcer, and did not consider pressure ulcer grade. The Committee noted that the External Assessment Centre's revisions simplified the treatment pathways and included weighted mean lengths of stay rather than median values. It considered that analysis based on these revisions was more appropriate, in the context of the data available.

5.18 The Committee accepted that the mean length of stay values calculated by the External Assessment Centre – adjusted to account for differences in patient characteristics between the groups – were appropriate. However, the Committee noted that the calculated adjusted mean length of stay values were inconsistent, due to the limited information available on patient characteristics. The Committee acknowledged that the relationship between length of stay and pressure ulcer incidence and severity is not straightforward and there are many other factors that can influence length of stay. The Committee concluded that further research would be necessary to determine the system impact of using Parafricta Bootees and Undergarments in hospital. It considered that more detailed information on the length of stay, severity of pressure ulcers, the costs of treating them, pressure ulcer status and where a patient is cared for after discharge could be used to inform a more robust cost analysis.

5.19 The Committee noted that a very simple approach was adopted for the cost analysis in the community model. It was aware that the only data available were those from the Smith and Ingram (2011) study that was conducted in hospital. The Committee considered that the cost savings from the community model were uncertain, but it nevertheless acknowledged the potential for significant cost savings with the use of Parafricta garments in the community if further research demonstrates their effectiveness in reducing the incidence and severity of pressure ulcers in hospital.

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 6 Conclusions

6.1 The Committee concluded that Parafricta Bootees and Undergarments are a promising technology with the potential to reduce skin damage and the incidence and severity of pressure ulcers in both hospitals and the community. However, the Committee considered that more evidence about the clinical benefits of using the garments is needed to support the case for more widespread, routine adoption.

6.2 The Committee recommended that further research into clinical outcomes with Parafricta Bootees and Undergarments would be beneficial. It considered that comparative research against standard care could determine whether using Parafricta garments prevents skin damage and the development of pressure ulcers, and whether it benefits patients with existing pressure ulcers of all grades. The Committee considered that in order for the garments to be used in those most in need, research should address how best to identify patients at risk of pressure ulcers due to friction and shear, for whom the use of Parafricta garments would offer most benefit.

6.3 The Committee considered that research could be completed relatively quickly, especially in the NHS centres that are already using the technology. Of the outcomes defined in the scope, it considered that the reduction in pressure ulcer incidence and severity, length of hospital stay, ease of use and patient comfort would be particularly important in any research or data analysis.

Andrew Dillon
Chief Executive
November 2014

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 7 Committee members and NICE lead team

## *Medical Technologies Advisory Committee members*

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

**Professor Bruce Campbell (Chair)**
Consultant Vascular Surgeon, Royal Devon and Exeter Hospital

**Dr Peter Groves (Vice Chair)**
Consultant Cardiologist, Cardiff and Vale UHB

**Professor Dilly Anumba**
Chair of Obstetrics and Gynaecology/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

**Ms Susan Bennett**
Lay member

**Dr Keith Blanshard**
Consultant Interventional Radiologist, Leicester General Hospital

**Professor Nigel Brunskill**
Professor of Renal Medicine, University of Leicester

**Mr Matthew Campbell-Hill**
Lay member

**Mr Andrew Chukwuemeka**
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

**Professor Daniel Clark**
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

**Professor Tony Freemont**
Professor of Osteoarticular Pathology, University of Manchester

**Professor Shaheen Hamdy**
Professor of Neurogastroenterology, University of Manchester

**Dr Jerry Hutchinson**
Independent Medical Technology Adviser

**Dr Cynthia Iglesias**
Health Economist, University of York

**Professor Mohammad Ilyas**
Professor of Pathology, University of Nottingham

**Dr Greg Irving**
General Practitioner and Clinical Lecturer, University of Cambridge

**Dr Eva Kaltenthaler**
Reader in Health Technology Assessment, ScHARR, University of Sheffield

**Dr Paul Knox**
Reader in Vision Science, University of Liverpool

**Mrs Karen Partington**
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

**Mr Brian Selman**
Managing Director, Sectra Ltd

**Professor Wendy Tindale**
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

**Professor Allan Wailoo**
Reader in Health Economics, ScHARR, University of Sheffield

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

**Mr John Wilkinson**
Director of Devices, Medicines and Healthcare Products Regulatory Agency

**Dr Janelle Yorke**
Senior Lecturer in Nursing, University of Manchester

## *NICE lead team*

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

**Jo Burnett and Ailish Higgins**
Technical Analysts

**Bernice Dillon**
Technical Adviser

**Deborah Gleeson and Jackie Stephen-Haynes**
Lead Expert Advisers

**Mohammad Ilyas**
Non-Expert MTAC Member

**Catherine Meads and Matt Glover**
External Assessment Centre Representatives

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

# 8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Birmingham and Brunel:

- Meads C, Glover M, Pokhrel S. Parafricta Bootees and Undergarments to reduce skin breakdown in people with frail skin or at risk of pressure ulcers, April 2014

Submissions from the following sponsor:

- APA Parafricta

The following individuals gave their expert personal view on Parafricta Bootees and Undergarments by providing their expert comments on the draft scope and assessment report.

- Mr George Dunn, ratified by The Society of Chiropodists and Podiatrists – clinical expert
- Ms Deborah Gleeson, ratified by Wound Care Alliance UK – clinical expert
- Dr Jane McAdam, ratified by The Society of Chiropodists and Podiatrists – clinical expert
- Mr Glenn Smith, nominated by the Southern Alliance of Tissue Viability Nurses – clinical expert
- Professor Jackie Stephen-Haynes, nominated by the Wound Care Alliance UK – clinical expert
- Professor Peter Vowden, nominated by the European Wound Management Association – clinical expert

The following individuals gave their expert personal view on Parafricta Bootees and Undergarments in writing by completing an expert adviser questionnaire provided to the Committee.

- Emma Bond, ratified by The Vascular Society – clinical expert
- Professor Michael Clark, ratified by the European Wound Management Association – clinical expert
- Ms Judy Harper, ratified by the Royal College of Nursing – clinical expert
- Samantha Holloway, ratified by the European Wound Management Association – clinical expert

© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).

## About this guidance

This guidance was developed using the NICE medical technologies guidance process.

It has been incorporated into the NICE pathway on pressure ulcers.

We have produced a summary of this guidance for the public. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

### Related NICE guidance

For related NICE guidance, please see the NICE website.

### Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

### Copyright

© National Institute for Health and Care Excellence, 2014. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-0833-2

## *Accreditation*


© NICE 2018. All rights reserved. Subject to Notice of rights (https://www.nice.org.uk/terms-and-conditions#notice-of-rights).