National Institute for Health and Care Excellence

Medical Technologies Evaluation Programme

MT216 Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers

Consultation Comments table

MTAC date: 11 September 2014

There were 19 consultation comments from 4 consultees (3 NHS professionals and 1 manufacturer). The comments are reproduced in full.

Table 1

<table>
<tr><th>Com. no.</th><th>Consultee number and organisation</th><th>Sec. no.</th><th>Comments</th><th>Response</th></tr>
<tr><td rowspan="4">1</td><td rowspan="4">1. Sponsor</td><td rowspan="4">Introduction 1.1
Page 2</td><td colspan="2">Based on appraisal of the total body of evidence presented APA Parafricta believes that the following recommendation is supported.</td><td rowspan="4">Thank you for your comment.

For clarity, and ease of response, the remainder of this comment has been subdivided by the MTEP team and is shown as comments 1a to 1h. No changes have been made to the submitted text.

The Committee considered changing the recommendation in the guidance to a positive recommendation for Parafricta Bootees for people at risk of developing a pressure ulcer in the heel, as requested by the sponsor. The Committee was</td></tr>
<tr><td>Case for adoption and potential benefits</td><td>Type of recommendation(s) which are normally made</td></tr>
<tr><td>Case for adoption is partially supported and technology has potential to provide significant patient or healthcare system benefits</td><td>Recommendation for use in specific circumstances and recommendation for development of further evidence</td></tr>
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			The specific circumstance proposed is: **"PARAFRICTA BOOTEES MAY BE USED TO REDUCE SKIN BREAKDOWN IN ADULTS AT RISK OF PRESSURE ULCERS OF THE HEEL, IN ADJUNCTIVE USE WITH PRESSURE REDISTRIBUTION"** **It is our belief that this can be justified as follows:**	presented with all available clinical and economic evidence, including some additional clinical data provided on an academic-in-confidence basis. The Committee made its decision based on this evidence and advice from clinical experts, in line with the methods of the Medical Technologies Evaluation Programme. The Committee decided not to change Section 1.1 because the evidence presented was not sufficiently compelling, and that more evidence was needed to prove the clinical effectiveness of both Parafricta Bootees and Undergarments before they could be recommended for routine adoption in the NHS.
1a	1. Sponsor	Introduction 1.1 Page 2	**1. There is an urgent clinical need for products to address friction and shear** Friction and shear stresses are acknowledged by the Committee and NICE guidelines as important contributing factors in the formation of skin damage and pressure ulcers and yet there are no products recommended to address friction and shear stresses. There is clearly an unmet clinical need.	The Committee decided not to change section 1.1 because n section 4.4 of the guidance already summarised its considerations on the unmet need represented by skin damage due to friction and shear Section 4.4 states that '….that recent progress in pressure ulcer care has focused on the use of pressure-reducing and pressure re-distributing devices, but that many patients remain at risk of a pressure ulcer caused by friction and shear.'
1b	1. Sponsor	Introduction 1.1 Page 2	**2. Parafricta technology has been designed and demonstrated to address friction and shear** The Committee also acknowledges that Parafricta bootees (and undergarments) are the only products available that incorporate technology which specifically addresses the	Please refer to the response to comment 1.

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			reduction of friction and shear stresses.	
1c	1. Sponsor	Introduction 1.1 Page 2	**3. The entirety of clinical evidence available for the use of the bootees to protect heels is compelling** The entirety of clinical evidence available for the use of the bootees to protect heels is compelling, when the results from the following sources are taken together: i. Gleeson (2014) - we are aware that the data held at St Helens and Knowsley Trust now covers two years of use of the bootees and we understand that Gleeson will also submit this new information to NICE during the public consultation ii. The evidence provided by the experts to the Committee iii. Supplementary information and data analysis provided by the sponsor iv. Hampton et al (2009) v. Smith and Ingram (2010) **vi.** The source data from Smith and Ingram provided to EAC by Smith	Please refer to the response to comment 8 in relation to the additional data provided by Gleeson (2014) [Appendix 1]. All sources of information described by the consultee were carefully considered by the Committee. Section 3.12 of the guidance states that '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.'
1d	1. Sponsor	Introduction 1.1 Page 2	**4. The quality of evidence provided is sufficient** The Committee acknowledged that there is a lack of good quality evidence about standard care practice and that the quality of evidence for	The Committee noted in section 3.10 of the guidance that '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

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			products used in pressure ulcer prevention and management is often not extensive. The level of scrutiny applied to Parafricta products as options for the management of friction and shear stress, seems at odds, therefore, with that applied to products such as sheepskin or silicone gel pads which the Committee notes are options for pressure management for heels.	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.' The evidence for products such as sheepskin or silicone gel pads has not been evaluated. The Committee have made no recommendations or judgements about these products.
1e	1. Sponsor	Introduction 1.1 Page 2	**5. Use of the bootees could deliver substantial cost benefits** The acknowledgement by the committee that the cost-benefits calculated for the use of Parafricta are "conservative" and that other quality of life benefits will likely increase the benefits that could accrue to the National Health Service by adoption of this technology.	The Committee made a research recommendation in section 1.1. This recommendation recognises the potential for Parafricta garments to provide benefits to the NHS. However, the Committee decided that there was not sufficient evidence available to quantify those benefits. The Committee noted in section 4.6 that '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.…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.' Please also refer to Committee considerations 5.17-5.19.
1f	1. Sponsor	Introduction 1.1 Page 2	**6. It is possible to define patient selection criteria** It is possible to more clearly define those	The Committee considered comment carefully and was advised by experts who use Parafricta garments both in the community and in hospital that they use

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			patients at particular risk of heel pressure ulcers for which friction and shear stresses are contributing factors, by the use of locally adopted guidelines developed from published literature and clinical experience (in addition to the use of internationally validated risk-assessment scales such as Waterlow, Maelor, Norton and Braden) and therefore limit use to the patients most likely to benefit, as has been done some of the Trusts currently using Parafricta bootees.	locally developed protocols to identify people at high risk of developing pressure ulcers due to friction and shear. However, it decided not to change section 1.1 because section of the guidance already describes the Committee's considerations.
1g	1. Sponsor	Introduction 1.1 Page 2	**7. Equality issues should be considered** Equality issues may have been insufficiently considered, since friction damage to heels is particularly associated with the frail skin of the elderly, adults with repetitive movements (such as in Huntington's Disease and Alzheimer's Disease) and adults with neurocognitive impairments (where the bootees may provide the most patient-acceptable means of protecting the heels from damage).	In the Equality Impact Assessment published alongside the Medical Technologies Consultation Document, it was noted that: - No equality issues were identified in the sponsor's submission or patient organisation questionnaires. No patient organisation questionnaires were received; - Although the device may have particular advantages for people with chronic wounds, the use of it will not exclude any groups of people; - There is no potential for the recommendations to have an adverse impact on people with disabilities, and there are no barriers or difficulties with access for any specific group. The population defined in the guidance scope (section 3) includes "People (adults or children of any age) in a community or hospital setting who do not have a pressure ulcer but are at risk of developing pressure ulcers caused by friction and shear forces, including but not limited to patients who have frail skin and are at risk of skin breakdown or damage". The following sub-group was specified in the scope:

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				"people who may have skin damage due to musculoskeletal or neurological conditions where repetitive motion is present". No evidence relating to this subgroup was submitted and no barriers to access for this group or those mentioned by the consultee have been identified. The Committee considered that Parafricta garments may particularly valuable to older people and those with frail skin, as they are more susceptible to pressure ulcers as a result of friction and shear. The Committee decided to change section 3.12 to further clarify the particular benefit Parafricta garments may have for these populations.
1h	1. Sponsor	Introduction 1.1 Page 2	**8. Its use is not supported in children** Effectiveness in children had not been demonstrated in any studies to date (hence the proposed limitation to adults).	The Committee considered restricting recommendations about Parafricta garments to adults only. The Committee noted that the population defined in the guidance scope (section 3) was "People (adults or children of any age)." The cost analysis submitted by the sponsor described the patient population as "people (adults or children of any age)". It also noted that limiting any recommendation to adults only would introduce a potential barrier to access for children. The Committee decided to change sections 1.1 and 5.3 to refer to "people", instead of specifying "adults and children" to further clarify the scope of the guidance.
2	4. NHS Professional (Expert Adviser)	1.1	Case for adoption is partially supported and technology has potential to provide significant patient or healthcare system benefits Recommendation for use in specific circumstances	Thank you for your comment. Please refer to the response to comment 1.

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			and recommendation for development of further evidence PARAFRICTA BOOTEES MAY BE USED TO REDUCE SKIN BREAKDOWN IN ADULTS AT RISK OF PRESSURE ULCERS OF THE HEEL, IN ADJUNCTIVE USE WITH PRESSURE REDISTRIBUTION.	
3	1. Sponsor	1.2	Reads: 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 secondary care for ease and speed of generating findings. The research should include development of criteria to recognise people who would most benefit from the technology in community and secondary care. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will review this guidance when substantive new evidence becomes available. Suggest: **Parafricta bootees may be used to reduce skin breakdown in adults at risk of pressure ulcers of the heel, in adjunctive use with pressure redistribution. However the committee recommends further research is carried out to address uncertainties about the claimed patient and system benefits of using Parafricta Undergarments and the use of Parafricta Bootees in patients who have developed heel pressure**	Thank you for your comment. Please see the response to comment 1. In facilitating collaborative research, NICE actively involves all stakeholders in determining the type of research product which would address the evidence gaps. All of the consultee's suggestions will be considered after publication of the guidance.

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			ulcers. This should take the form of comparative research against standard care, preferably carried out in secondary care for ease and speed of generating findings**. Consideration should be given to the** development of criteria to recognise people who would most benefit from the technology in community and secondary care. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will review this guidance when substantive new evidence becomes available. Suggestions for further initial involvement by the sponsor include: 1. Further analysis of the Gleeson and Smith & Ingram data Drawing from the comments made by the EAC and the Consultation document, we would particularly welcome participation of NICE in further statistical analysis of (1) the continuing analysis of results obtained by Gleeson in introducing the bootees into routine practice at St. Helen's & Knowsley NHS Trust since 2012 and (2) the existing data underlying the Smith & Ingram (2010) publication 2. Guidance in type of patient who would most likely benefit We would also be willing to participate in developing guidance from NICE and its advisors in defining the type of patient who would most likely benefit from using Parafricta bootees and undergarments, as per Section 6.2 of the Consultation document.	

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4	1. Sponsor	2.5	Reads: “They include: dynamic or static high-specification pressure-relieving or pressure-redistributing beds, mattresses, overlays and cushions: and sheepskin or pressure relieving bootees or silicone gel pads (numerous products, shapes and sizes are available). Suggest **adding**: The Committee noted that NICE clinical guideline #179 does not, however, specifically recommend the use of sheepskin or pressure relieving bootees or silicone gel pads to prevent heel pressure ulcers, but “to discuss with adults with a heel pressure ulcer and, if appropriate, their carers, a strategy to offload heel pressure as part of their individualised care plan.”	Thank you for your comment. NICE clinical guideline 179 recommends; : • Section 1.1.15, page 14: ‘Discuss with adults at high risk of developing a heel pressure ulcer and, where appropriate, their family or carers, a strategy to offload heel pressure, as part of their individualised care plan.’ • Section 1.2.19, page 18: ‘Discuss with children and young people at high risk of developing a heel pressure ulcer and their parents and carers, where appropriate, a strategy to offload heel pressure as part of their individualised care plan.’ • Section 1.4.26, page 23: ‘Discuss with adults with a heel pressure ulcer and, if appropriate, their family or carers, a strategy to offload heel pressure as part of their individualised care plan.’ • Section 1.5.24, page 27 ‘Discuss with the parents or carers of neonates and infants and with children and young people (and their parents or carers if appropriate), a strategy to offload heel pressure as part of their individualised care plan to manage their heel pressure ulcer, taking into account differences in size, mobility, pain and tolerance.’

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				http://www.nice.org.uk/guidance/cg179/resources/guidance-pressure-ulcers-prevention-and-management-of-pressure-ulcers-pdf Sheepskin and pressure-relieving bootees were included in the Parafricta scope at the suggestion of expert advisers. The Committee decided not to change section 2.5 because it was sufficiently clear that the options outlined in section 2.5 to manage the prevention and development of pressure ulcers are not those outlined in NICE clinical guideline 179, but simply a summary of the management options currently available in the NHS. NICE clinical guideline 179 is discussed in sections 2.6 and 2.7.
5	1. Sponsor	3.4 Page 8 Line 3	Reads: “the authors concluded that Parafricta garments were effective in reducing oedema.” Suggest: “the authors concluded that Parafricta garments were effective in reducing oedema, **and hence tissue damage, which clearly evidenced improvement in clinical outcomes**.”	Thank you for your comment. In response to this consultation comment, the External Assessment Centre (EAC) reviewed their original assessment. They stated that the evidence provided in the Hampton study (2009) did not evaluate tissue damage, but did evaluate oedema. The Committee decided to update section 3.4 to further clarify the description of the study.
6	1. Sponsor	3.4 Page 8 Line 10	Reads “The colour photographs for both the heels and sacral areas were not considered clear enough by the researchers to validate the results.” Suggest **adding**: “and hence the reliance on more objective ultrasound measurements”.	Thank you for your comment. The External Assessment Centre (EAC) stated that neither they nor the sponsor relied on the colour photographs alone for the assessment of effectiveness or the economic evaluation.

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				The Committee decided to change section 3.4 to further clarify the description of the study.
7	1. Sponsor	3.8	Reads: "It is also unclear how much of the reduction in pressure ulcers reported was owing to Parafricta Bootees and how much to the other initiatives taking place at the NHS trust." **Sponsor Comment**: At the MTAC meeting on the 15th May, Gleeson, who was invited as an expert and is the author of this study, stated clearly that the hospital had not changed its practice and procedures with regard to the prevention of pressure ulcers other than by the addition of Parafricta bootees into routine care.	Thank you for your comment. Please refer to the response to comment 8.
8	3. NHS Professional (Expert Adviser)	3.8 Page 11	Reads: "The Committee considered data from an unpublished clinical audit by Gleeson (2014). The audit 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 are academic-in-confidence and are not reported. The External Assessment Centre noted that this was an unpublished manuscript of an interim report and some details were missing. For example, there is no information on the number of people who were allocated Parafricta Bootees. It is also unclear how much of the reduction in pressure ulcers reported was owing to Parafricta Bootees and how much to the other initiatives taking place at the NHS trust." As author of the manuscript I would like to add the following information [presented in Appendix 1], **in**	Thank you for your comment. The information submitted in support of this comment was accepted by NICE as academic-in-confidence and cannot therefore be fully published. The EAC assessed the additional information in full, and considered that the additional data was not sufficient to alter its existing view of the audit. The EAC felt that the lack of a concurrent comparator group made it impossible to identify how much of the reduction in pressure ulcers was due to Parafricta bootees, and how much was due to other initiatives occurring simultaneously in the Trust. [redacted]

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			academic confidence, in order to answer the questions posed by the MTAC.	The audit author (an Expert Adviser to the Committee) stated that the other Trust initiatives were long-standing and that she believed that the reduction in pressure ulcers could only be attributable to the use of Parafricta Bootees. The Committee decided to change sections 3.8 and 3.11 to include the further evidence submitted at consultation but did not change its existing view of the audit data.
9	1. Sponsor	3.11	Reads: "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." Suggest: "The Committee accepted the External Assessment Centre's critique of the Smith and Ingram (2010) study and agreed that because of potential confounding factors, **notwithstanding there was no significant difference in the Waterlow scores of the two cohorts,** it is not **sufficiently** clear that any change in the pressure ulcer incidence or severity was due to Parafricta garments **and would recommend that further, independent analysis of the source data is carried out to take into account any potential confounding factors not reported in the publication. It acknowledged that there can be practical difficulties in matching cohorts for all confounding factors.**"	Thank you for your comment. The EAC's critique of Smith and Ingram (2010) (page 25 of assessment report) noted that the Waterlow scores of the cohort without Parafricta placed them at an *a priori* higher risk than the cohort given Parafricta garments. The EAC judged that it was reasonable to assume from this study that the reason for differential effects from the two cohorts was likely to be due to confounding factors rather than clinical effectiveness of Parafricta garments. The Committee decided not to change section 3.11.
10	1. Sponsor	4.1	Reads: During the selection of Parafricta Bootees and Undergarments, the Committee received expert	Thank you for your comment.

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			advice, based on this study and from 3 years clinical practice, 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. Suggest: During the selection of Parafricta Bootees and Undergarments, the Committee received expert advice, based on this study and from 3 years clinical practice, 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 **considerations that had been addressed in the Trusts that had adopted Parafricta garments into routine use. However the simplicity of the products would likely make it less onerous than the introduction of many other technologies into the NHS.**	The Committee considered this comment carefully, but decided not to change section 4.1 because its considerations of the NHS impact of Parafricta Bootees and Undergarments were adequately described in sections 4.3 to 4.9.
11	1. Sponsor	4.6	Reads: 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 the 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 secondary care was required to inform a more appropriate cost analysis. **Sponsor Comment**: We agree with the experts who advised the	Thank you for your comment. In facilitating collaborative research, NICE actively involves all stakeholders in determining the type and design of research product(s) which would address the evidence gaps.

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			Committee that pressure ulcers of the more common grade 1 or 2 would be less likely to prolong the length of hospital stay, however we would add that this is unless complications set in, or they progress to grade 3 or 4. We also remind the Committee that (1) Parafricta may also assist in healing of pre-existing severe pressure ulcers and thus reduce hospital stays and (2) that whilst the grade 2 pressure ulcers may not always delay discharge from hospital, their ongoing treatment will have costs to the NHS in community care*. We agree with the Committee that future studies using length of stay as an endpoint should control for comorbidities to the maximum possible extent, but we require further support for the statement that collection of detailed resource use information on managing pressure ulcers in secondary care would assist in informing a more complete cost analysis. *Note: This issue of delay in hospital discharge and associated additional costs due to pressure ulcers is also confirmed by Professor Peter Vowden in the MT216 Correspondence log on p6.	
12	1. Sponsor	5.3 Line 2	Suggest: delete “children”	Thank you for your comment. Please refer to comment 1h. The Committee decided to remove specific references to adult and children populations in the guidance. The phrase “adults and children” has been removed from section 5.3 and replaced with “people”.
13	1. Sponsor	5.6 Line 8	Reads “The general hospital costs were £3265.33 per	Thank you for your comment.

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			day" Suggest "The general hospital costs were **£326.53** per day"	This was a typographical error. Section 5.6 of the guidance has been changed as suggested.
14	1. Sponsor	5.9	Reads: "The base-case results for the community model showed a cost saving of £3455 per person with a pressure ulcer." Suggest: "The base-case results for the community model showed an **annual** cost saving of £3455 per person with a pressure ulcer.	Thank you for your comment. The Committee decided that this was a helpful clarification, and agreed to change section 5.9 to clarify the nature of the stated cost saving.
15	1. Sponsor	5.17 Line 4	Reads: "However, it noted that the model did not include information on the resource implications of having a pressure ulcer and did not consider pressure ulcer grade." Suggest: "However, it noted that the model did not include **sufficient** information on the resource implications of having a pressure ulcer **of a particular grade.**"	Thank you for your comment. The External Assessment Centre stated that the model incorporated very limited information on resource use implications associated with pressure ulcers. Only additional dressing costs were considered and no distinction was made for pressure ulcer grade. The External Assessment Centre presented these opinions to the Committee. The Committee decided to change section 5.17 to further clarify the description of the cost model.
16	1. Sponsor	5.18 Line 4	Reads: "However the Committee noted the calculated adjusted mean length of stay values were inconsistent, probably due to the limited information available on patient characteristics". **Sponsor Comment:** We noted that this sentence is not clear in its meaning, and wish to remind the MTEP that we have not been provided with the detailed calculations made by the EAC that support the statements made in paragraph 5.18	Thank you for your comment. Detailed length of stay calculations are in Appendix 4 of the Assessment Report, including a description of the statistical model used to estimate adjusted mean lengths of stay, and the values obtained. The Committee decided not to make any changes to section 5.18 because the source and reliability of the calculated values were considered to be sufficiently clear.

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17	1. Sponsor	6.1 line 5	Reads: "...Committee considered there more evidence about the clinical" Suggest "...Committee considered **that** more evidence about the clinical"	Thank you for your comment. Section 6.1 has been changed in line with the suggestion.
18	1. Sponsor	6.2	Reads: 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 in most need, research should address how best to identify patients at risk of pressure ulcers, for whom the use of Parafricta garments would offer most benefit. Suggest: 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 **in the sacral and hip region**, and whether it benefits patients with existing pressure ulcers of all grades **in the heel, hip and sacral regions**. The Committee considered that in order for the garments to be used in those in most need**, consideration should be given to the** how best to identify patients at risk of pressure ulcers, for whom the use of Parafricta garments,	Thank you for your comment. Please refer to the responses to comments 1 and 2.

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			would offer most benefit.	
19	2. NHS Professional	General	The parafricta garments have proved to be very effective within my organisation. They have significantly reduced our incidence of Category 2 pressure ulcers caused by friction.	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or Advisory committees."

Appendix 1 Additional Information about the Gleeson (2014) audit provided by D. Gleeson [academic-in-confidence] [comment 8]

[redacted]