National Institute for Health and Care Excellence

External Assessment Centre correspondence

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

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Submission Document Section/Sub-section number	Question / Request *Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.*	Response *Attach additional documents provided in response as Appendices and reference in relevant cells below.*	Action / Impact / Other comments
General	5th March 2014 To all expert advisors Dear expert advisors I am contacting you because your names have been forwarded to me as experts who could help with the NICE MTEP assessment of parafricta for pressure ulcers. I am the lead reviewer for the External Assessment Centre – Birmingham & Brunel Collaboration. I would like to ask you your opinions on the best use of these bootees and undergarments. Also whether you consider that parafricta has any side effects or people in whom it should not be used. Many thanks for your help	1. 7th March 2014 from Debbie Gleeson. Hi Please see attached re uses and recommended pt groups. I believe there is no side effects and no groups who could not use the product. Regards Deb (see appendix 1 for the attached poster) 2. On 24th March, from Peter Vowden Dear Catherine One issue with all pressure relief equipment is the impact it has on the patient's ability to self reposition and move around the bed. Much of the equipment we have addresses the	**No specific action taken, informed report.** (NB didn't manage to speak to Glenn Smith on the phone)

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		offloading issues in pressure ulcer prevention but fails to address repositioning. Peter 3. HI Catherine DO you want to do this over the phone? Glenn Glenn Smith	
General	18th March 2014 To all expert advisors Dear all 1. We would like to ask you whether you think that having a pressure ulcer would be a reason for keeping a person longer in hospital? If they were admitted for a condition, we	1. 26th March, from Debbie Gleeson (responses in larger font) Dear all 1. We would like to ask you whether you think that having a pressure ulcer would be a reason for keeping a person longer in hospital? Not unless required specific treatments If they were admitted for a	**No specific action taken, informed report**

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	would assume that the discharge would be because of the condition rather than whether they had a pressure ulcer or not, would you agree or disagree with this? What characteristics of a pressure ulcer would lead you to delay discharge? Can a person be admitted just because they have pressure ulcers, when their underlying condition is stable? Particularly if it was a grade 1 or grade 2 ulcer? 2. How many times can a patient reuse a garment? We imagine that you would use a bootee for some days then wash it? How many days would you have it on before washing? Similarly for undergarment - how many undergarments per patient would you use? How many times would you be able to wash and reuse	condition, we would assume that the discharge would be because of the condition rather than whether they had a pressure ulcer or not, would you agree or disagree with this? What characteristics of a pressure ulcer would lead you to delay discharge? Infection, deterioration, osteomylitis Can a person be admitted just because they have pressure ulcers, when their underlying condition is stable? Particularly if it was a grade 1 or grade 2 ulcer? Not for 1 or 2,s but could for 3 and 4,s 2. How many times can a patient reuse a garment? we have reused numerous times in excess of ten pt.s We imagine that you would use a bootee for	

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	before it was no longer useable? Could you ever wash and use on another patient? If you wash the undergarments on a very hot cycle, does the elasticated bit deteriorate? 3. Do you have anything on how you quantify deterioration in pressure ulcers? Kind regards Catherine	some days then wash it? How many days would you have it on before washing? 7 or replace if soiled. Similarly for undergarment - how many undergarments per patient would you use? difficult to state not had a lot of experience with undergarments How many times would you be able to wash and reuse before it was no longer useable? Could you ever wash and use on another patient? For booties yes If you wash the undergarments on a very hot cycle, does the elasticated bit deteriorate? cant answer 3. Do you have anything on how you quantify deterioration in pressure ulcers? yes appearance, infection, depth of tissue loss, increase in grade	

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		i.e. from grade 3 to 4 ect. Kind regards Catherine 2. 21st March, from Peter Vowden Dear Catherine 1. Developing a pressure ulcer is a frequent cause of delayed hospital discharge and attracts considerable additional inpatient costs as well as raising quality issues and potential litigation. Cost issues have been addressed in several papers (Bennett G, Dealey C, Posnett J. The cost of pressure ulcers in the UK. Age and ageing. 2004;33(3):230-5.; Dealey C, Posnett J, Walker A. The cost of pressure ulcers in the United Kingdom. Journal of wound care. 2012;21(6):261-2, 4, 6.). Pressure ulcer category (3 or above), the presence of sepsis, impact on mobility	

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		and additional home care requirements would all delay discharge. The majority of pressure ulcers actually occur in the community. It would be unusual for a Category 1 or 2 pressure ulcer to cause admission but more severe pressure ulcers can, especially if they are the source of sepsis. 2. Bootees should not require frequent changing and should be suitable for wipe cleaning with full wash between cases. Frequency of change for undergarments would depend on continence. The company should be able to provide reuse and wash data. 3. The only tool there is is the grading system. Progress from Category 2 to 3 represents deterioration.	

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		Peter	
Clinical audit (Gleeson 2014)	24th March 2014 to Debbie Gleeson Dear Debbie I wonder whether you might be willing to share your manuscript on parafricta with me? It would all be completely academic in confidence. We could use it for the NICE evaluation that is underway at the moment. Kind regards. Dr Catherine Meads	25th March, from Debbie Gleeson. Hi Yes of course. Regards Deb Word document with unpublished manuscript attached (see appendix 2)	**Used manuscript in report (Gleeson 2014)**
Clinical effectiveness of Loehne (2013) case series poster	From: Catherine Meads Sent: 06 March 2014 18:29 To george.sampson Subject: Harriet Loehne poster Dear George Do you have any contact with Harriet Loehne? I have been assessing her poster and there is very little information about the case series she conducted. If you have her contact details please could you forward	From: George Sampson Sent: 07 March 2014 Hi Catherine, Details below for Harriett; she has left her clinical post and started her own company, but I am sure she is more than happy to give you the details of her	**None as no information sent**

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	them? Many thanks Catherine From: Catherine Meads Sent: Mar 10, 2014 11:11 AM To: Harriet Loehne CcSubject: FW: Harriet Loehne poster Dear Harriett I am assessing the evidence for parafricta bootees and undergarments on behalf of NICE Medical technologies Evaluation Pathway and your poster at SAWC 2013 has been forwarded to us. Unfortunately the poster has no details of the patients and their outcomes. Do you have any of the following details you could forward to us? Number of US nursing home patients, information on sex, age, current condition,	work. Harriett B. Loehne & Associates, LLC **From:** Harriett Loehne Hi Catherine, I apologize for delay in reply. I have been on vacation, and now still am traveling without access to my data. I will be glad to send you what I have when I return home at the end of next week. I have retired from the Medical Center, however, so do not have the current conditions on anyone. Thanks, Harriett	

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	duration, grade or site of pressure ulcers. Numerical results of treatment. Kind regards Catherine Reference: Loehne, H.B. Clinical study of device to assist in prevention of heel and foot pressure ulcers resulting from friction and shear in patients unable to utilize heel pressure relieving devices. Poster presentation, SAWC Spring Meeting (USA). 2013. 20th March 2014 To Harriet Loehne Hi Harriet Thanks for getting back to me and I look forward to seeing what information you do have on the participants in your study. The current conditions were at the time of the study rather than now. Kind regards Catherine	No response	

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Economic model	**From:** Subhash Pokhrel **Sent:** 24 April 2014 11:09 **To:** 'George Sampson'; Catherine Meads **Cc:** 'Joanne Burnett'; 'Bernice Dillon'; Matthew Glover **Subject:** RE: Some questions about the Parafricta model Dear George, We have one question for you about the Parafricta model. In Table C6 of the submission, it is stated that the cost in the community would be 3 garments on a wear/wash/standby cycle = 3x £35.14 = £105.42. However in the body of the report (and the figure used in the model) the stated cost is £80. Please can you explain exactly what you mean by £80 and how you derived this?	Sent 24th March To Subhash, I have asked my colleague, Mike Clark, who constructed the model and he responded: *Note that the £80 refers to the community model and is the average annual cost per at risk patient. It is a rounded figure in view of the nature and accuracy of the model.* *Reference to Table C6 shows that both 2x35.14 and 3x35.14 are considered.* *The £80 is obtained from 2x35.14+9.72, the £9.72 being a notional allowance for the average annual cost of washing. The choice of two is rationalised by reference to our retail experience that users on average*	**Input to appraisal committee discussions**

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	We would appreciate your prompt response. Many thanks in advance. Subhash.	*have two items replaced annually.* *Non-rounded figures are used in the hospital model since (a) it is per patient-episode and (b) it is most likely more accurate.* *It is in any case open to vary these parameters in the model to explore alternatives.* Best Regards George	

[Insert additional rows if required]

Appendix 1

Pdf of Heel Pressure Ulcer Risk Protocol sent by Debbie Gleeson on 7th March

St Helens and Knowsley Teaching Hospitals NHS
NHS Trust

Heel Pressure Ulcer Risk Protocol

Pressure ulcers develop as a consequence of 3 factors: pressure / friction / shear. Whilst most prevention strategies and equipment will remove or lower these factors i.e. pressure relieving mattresses and slide sheets, additional strategies (Parafricta® Bootees) are required for those patients at risk of heel pressure ulcers as a direct consequence of an increased risk of shear forces and friction and or a lower tolerance to withstand these risk factors which contribute significantly to the formation of pressure ulcers.

Pressure Risk Assessment Maelor Score

RISK	EQUIPMENT	MAELOR SCORE	
LOW	PRESSURE REDUCING FOAM MATTRESS CONSIDER ROUNDING TOOL	0 - 19	
MEDIUM	DYNAMIC AIR MATTRESS CONSIDER ROUNDING TOOL	20 - 25	
HIGH	DYMAMIC AIR MATTRESS ETC: ROUNDING TOOL	25 - 36	

High Risk Groups for Heel Pressure Ulcers

1. Previous or current heel ulcer – reduced tissue tolerance.
2. Diabetes – peripheral neuropathy and numbness.
3. Stroke/ CVA – limited ability to move one or both legs and neuropathy changes.
4. Paralysis – leads to insensibility and atrophy and skin thinning.
5. Hip fracture – dragging injuries from knee replacements / digging the heel into the mattress to prevent sliding down the bed.
6. Dementia – cognitive impairment – risk of rubbing injuries.
7. Peripheral vascular disease – decrease vascular supply and reduces tolerance of mechanical forces.
8. Leg spasms/ Parkinson's / tremors – rubbing heels on the bed surfaces.
9. Agitated –heels on the bed / surfaces.
10. Leg oedema – compromised capillary flow and reduced tissue tolerance.
11. Frequently slides down bed or chair – poor posture in the chair or bed – risk of rubbing injury.

Parafricta® Bootees

Size Guide (shoe size)

X-Small = 2 to 3½
Small = 4 to 5½
Medium = 6 to 8½
Large = 9 to 10½
X-Large = 11 to 13

Appendix 2.

An manuscript sent by Debbie Gleeson on 25th March was marked academic in confidence