NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG20: Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers

This guidance was issued in November 2014.

NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

1. Decision

Amend the guidance to reflect the new evidence on Parafricta.

A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper.

2. Original objective of guidance

To assess the case for adoption of Parafricta for reducing skin breakdown in people with or at risk of pressure ulcers.

3. Current guidance

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.

4. Rationale

The original guidance recommended further research to address uncertainties about the claimed benefits using the technology. Up to date, there is limited evidence since the publication of the guidance (3 publications on 2 studies). There is no new comparative evidence evaluating the use of Parafricta bootees or undergarments compared with standard care.

5. New evidence

The search strategy from the original assessment report was re-run. References from November 2014 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of new evidence are presented in section 5.3 and 5.4. See Appendix 2 for further details of unpublished studies.

Searches were conducted on the FDA Maude and MHRA websites.

5.1 Technology availability and changes

The technology is still available. There is no functional change to the technology, and no change to the care pathway, the regulatory status and the cost of the technology since MTG20 was published.

5.2 Clinical practice

The NICE pathway outlines management and prevention of pressure ulcers in different population groups.

NICE clinical guidance on pressure ulcers: prevention and management (2014) recommends to develop and document an individualised care plan for people who have been assessed as being at high risk of developing a pressure ulcer, taking into account: the outcome of risk and skin assessment; the need for additional pressure relief at specific at-risk sites; their mobility and ability to reposition themselves other comorbidities and patient preference when preventing ulcers. The guideline also states that tailored information should be provided to people who have been assessed as being at high risk of developing a pressure ulcer, and their family or carers. Training should be provided for healthcare professionals on preventing a pressure ulcer.

NICE has produced the following medical technologies guidance for preventing pressure ulcers:

- MTG40: Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers (2019)]. Further research is recommended to address uncertainties about the claimed benefits of using Mepilex Border Heel and Sacrum dressings.
- MTG51: SEM Scanner 200 for preventing pressure ulcers (2020). Further research is recommended to address uncertainties about the clinical benefits of using the scanner compared with standard risk assessment

5.3 NICE facilitated research

A randomised controlled trial was commissioned by NICE (NCT04023981) after the publication of the guidance. MTEP commissioned Cedar to undertake this work.

The trial aimed to compare using Parafricta bootees in addition to standard care (SC) for preventing heel pressure ulcers (HPUs) with standard care alone in people at high risk of pressure ulcers. Patients were randomised to

either arm by [redacted] Patients were assessed (examination of patients' heels) on Day 0, Day 3 and Day 14 using the technology.

[redacted] A study report has been made available to NICE [redacted]

5.4 New studies

New evidence published since the guidance consisted of:

Gleeson (2015) is a non-comparative study. The study evaluated the use of Parafricta bootees over a 2-year period at Whiston Hospital, St Helens and Knowsley Teaching Hospitals NHS Trust. The bootees were introduced into the hospital in 2012 and was used in 6 wards at hospital among people with a high risk of getting a pressure ulcer. Results suggested that there was a decrease in the number of grade 2 pressure ulcer since the introduction of Parafricta boots with a reduction in the incidence of heel ulcers of 32% across all wards in the hospital, not just the six wards where the bootees were first used in the 2011 to 2013 period. ulcer incidence is likely linked to the use of

Parafricta bootees. The study was supported by the company. The author is also described as the inventor of the bootees in a press article (Weston 2016).

Gleeson (2016) is a 5-year follow-up study (2011 to 2015) and reported further results in Gleeson (2015). Compared to the baseline year, 2011, the incidence of pressure ulcers declined by 32% when Parafricta was introduced in 2012, by a further 67% in 2013 when education was introduced. After remaining static in 2014, pressure ulcers declined by a further 27% in 2015. Over the 5-year period the incidence of pressure ulcers fell by 84%. The study also reports an economic assessment of the interventions which reports that in the first year (2014-bootees alone) there was a saving compared to 2011 of £53,371, and in 2015, nearly £150,000. The author appears to be the inventor of the technology, but this was not declared in the paper.

Schofield (2018) a summary of the evidence and technology that contains new observational data on 15 patients across care settings (residential care homes, community hospitals, and a stroke ward in a community hospital). Parafricta bootees were introduced alongside existing treatments including specialised mattresses, repositioning and offloading. The study reported that patients rated the technology as excellent (n=14) or good (n=1). All non-blanching and blanching erythema fully resolved to normal intact skin after 3 to 4 days, the product was easy to use and there were no issues with compliance. Pressure mapping suggested a significant reduction in peak pressure on heels and other areas of the feet that were in direct contact with a surface when the Parafricta bootees were applied.

5.5 Cost update

There is no change made to the cost of the technology. The EAC did not conduct an analysis of costs.

The cost case in the original guidance remains valid. There has been a slight inflationary increase in the cost of Parafricta from £35.14 to £35.50. The price of the general dressing (74p) and extra bed days (£325) are most likely to increase also. The original guidance suggested considerable cost savings from the use of Parafricta in both the hospital (EAC base case, £595 per

person) and community settings (EAC base case, £2510 per person). The inflationary changes are unlikely to have significant impact on the cost case.

6. Summary of new information and implications for review

The new published clinical evidence supports the committee's clinical conclusions from the original guidance, showing that Parafricta Bootees and Undergarments could potentially reduce the development and progression of skin damage caused by friction and shear in people with, or at risk of, pressure ulcers. But new evidence is limited in quantity and quality with no comparative evidence demonstrating patient and system benefits of using Parafricta Bootees and Undergarments against standard care.

The unpublished study commissioned by NICE suggested that fewer people developed pressure ulcers using Parafricta compared with standard care. But the study has several limitations: early termination due to a recruitment difficulty; the allocation was not masked; small sample size; and short study follow-up.

There were no reports on the MHRA website. No entries related to the technology were found on the FDA Maude website.

An amendment to the guidance is recommended to reflect new evidence on the use of the technology.

7. Implications for other guidance producing programmes

There is an option within the MTEP process to update the guidance within another piece of NICE guidance. There is no existing technology appraisal guidance relevant to Parafricta, therefore this is not considered further. The NICE clinical guideline on pressure ulcers: prevention and management (CG179) was published in 2014. NICE may update the guideline to reflect current clinical practice, and no decision for commissioning the update was made.

Other relevant NICE guidance see Appendix 2.

8. Implementation

The company notes that 73 NHS hospitals have bought Parafricta products since June 2019.

9. Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were raised in the original guidance.

Review decision sign off:

Chris Chesters, Acting Associate Director Medical Technologies Evaluation

Contributors to this paper:

Technical analyst:	YingYing Wang
Technical adviser:	Chris Pomfrett
Acting Associate Director:	Chris Chesters
Project Manager:	Sharon Wright
Coordinator:	Joanne Heaney

Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	Yes
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	No
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

NICE clinical guidance (CG179) Pressure ulcers: prevention and management. April 2014.

NICE Medical technology guidance (MTG51) SEM Scanner 200 for preventing pressure ulcers. October 2020.

NICE Medical technology guidance (MTG40) Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers January 2019.

NICE Medical technology guidance (MTG17) The Debrisoft monofilament debridement pad for use in acute or chronic wounds Published March 2014 and updated March 2019.

In progress

Multiple sclerosis in adults: management NICE guideline. Publication

expected July 2022.

Allantoin for untreated epidermolysis bullosa (Topic selection ID number 8304) NICE technology appraisal guidance. Status: A-List - STS

Oleogel-S10 for treating epidermolysis bullosa (Topic selection ID number ID9875) NICE technology appraisal guidance. Status: A-list - STS

Registered and unpublished trials

The only unpublished trial identified by the search is NCT04023981, which

has been reported in section 5.3.

Trial name and registration number	Details
NCT04023981	This randomised study will assess whether Parafricta bootees, when used in addition to normal standard care, can reduce the incidence of heel PUs in patients at very high risk of skin breakdown. Recruitment Status: Terminated (Difficulties in recruiting eligible participants). Study completion date: 2018 Estimated enrolment: 31 participants Location: UK Funder/Sponsor: Cardiff and Vale University Health Board.

Appendix 3 – changes to guidance

Table 1: proposed amendments to original guidance

Section of MTG	Original guidance	Proposed amendment
Page 13 of 31, 3.16		For the guidance review, the External Assessment Centre reviewed published evidence since November 2014. There are 3 publications on 2 single-arm studies on the technology. No new evidence has been published that compared the use of Parafricta bootees or undergarments with standard care. Results suggested that there was a reduction in the incidence of heel ulcers of 84% across all wards in the hospital since the introduction of Parafricta bootees over a 5-year follow-up (Gleeson 2015 and 2016). A summary of the evidence on 15 people who used the Parafricta bootees reported a significant reduction in peak pressure on heels and other areas of the feet that were in direct contact with a surface, and people rated the technology highly (Schofield 2018). The External Assessment Centre considered that the new evidence does not answer the uncertainties resulting in research recommendations in this guidance. [2021].

References

[redacted].

Gleeson, D., 2015. Pressure-ulcer reduction using low-friction fabric bootees. British Journal of Nursing, 24(Sup6), pp.S26-S29.

Gleeson, D. 2016. Heel pressure ulcer prevention: a 5-year initiative using low-friction bootees in a hospital setting. Wounds UK, 12(4):80-87.

Schofield, A., 2018. Mitigating the damaging effects of tissue distortions by using a low-friction heel protector. British Journal of Nursing, 27(Sup12), pp.S27-S34.