

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. Review decision

The review of this guidance is deferred until October 2020.

2. Original objective of guidance

To evaluate the case for adoption of Parafricta bootees and undergarments to prevent the formation of pressure ulcers

3. Current guidance

Recommendations in MTG20:

“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

NICE has facilitated, through the MTEP research commissioning workstream, evidence generation on Parafricta which is expected to directly address the committee’s research recommendations. No other relevant evidence has been identified since the guidance was published nor has there been a change in the care pathway requiring an earlier review.

5. NICE-facilitated research

Following publication of this guidance NICE commissioned an External Assessment Centre to facilitate the research recommended in section 1, and described in more detail in section 6, of the [guidance](#):

The resulting pragmatic randomised controlled trial is on people at risk of pressure ulcers using the currently available product. Unsuccessful attempts to secure competitive funding for the trial led to delays; however the EAC (Cedar, Cardiff) have been awarded £0.24 M by Research for Patient Benefit (Wales) and the company has agreed to provide consumables. The proposed research has received a favourable multi-centre ethical opinion and the project has been accepted onto the NIHR portfolio. Scientific manuscripts arising from this study are expected to be complete in 2020 and will be available to NICE with anonymised patient-level detail.

6. Equality issues

No equality issues were raised in the original guidance

Contributors to this paper:

Technical Adviser (Research Commissioning): Chris Pomfrett

Technical Adviser (Evaluation): Bernice Dillon

Programme Manager: Lee Dobson

Associate director (MTEP) **Mark Campbell**