NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

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

1 Technology

1.1 Description of the technology

The Parafricta bootees and undergarments (APA Parafricta) are intended to reduce the potential for both the development and progression of skin damage as a result of friction and shear. This includes the development and progression of pressure ulcers and the risk of skin damage in people with frail skin or those who have medical conditions in which skin frailty is a primary factor. The bootees provide protection for the heel and ankle, and the undergarments provide protection for the sacrum, buttocks and hips.

The items are made from the proprietary Parafricta fabric. This textile is designed to reduce the impact of shear stress and friction associated with movement. It has a friction coefficient[1] value of 0.2. This is lower than for most textiles which range between 0.3 and 0.7. A value of zero would mean no friction at all. Parafricta has an absence of stiction[2] which results in very little drag and so 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 wound occurrence. This mechanism of action is designed to be distinct from current methods which aim to manage or prevent pressure ulcers by reducing or re-

[1] The measurement of the amount of friction existing between two surfaces.

[2] The increased force needed to overcome skin sticking to a surface before sliding. Stiction is a threshold, not a continuous force, so this build-up results in a tug or jerk to the skin.

distributing pressure. Parafricta can be used as an adjunct to these devices which do not address friction or shear.

Parafricta devices are not friction-free since this would not enable patients to use the garments without slipping. The Parafricta fabric is used to protect the skin in areas most at risk and both the bootees and undergarments have nonslip areas to assist patient positioning and have Velcro opening features. The positioning of the Velcro fasteners and the flat seams is designed to minimise skin creasing or damage occurs. There is a panel on the outside back of the double layer undergarments, which protects the person's sacral region while still ensuring the efficacy of the low friction/shear components inside. The bootees are available in a range of sizes, in slip-on or with Velcro fasteners and have non-slip soles. The undergarments are available in several sizes in slip-on or Velcro format, and as briefs or boxer shorts.

The Parafricta fabric is described as breathable but durable. The products are reusable following laundering in accordance with garments for NHS use.

1.2 Regulatory status

The Parafricta bootees and undergarments are made from the proprietary Parafricta textile. These products received a CE mark in 2006 to reduce friction and shear in people with frail skin and those who have, or are at risk of developing pressure ulcers, and are classified as a Class 1 Medical Device.

The bootees and undergarments are listed in the Drug Tariff Part IX and can be prescribed on a standard FP10 prescription form.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- A reduction in pressure ulcer incidence in patients 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 and morbidity and mortality.

- A reduction in pressure ulcer severity in patients who have or develop early (stage I/II) pressure ulcers, thereby reducing or avoiding adverse impact on quality of life, pain, discomfort, hospital length of stay and morbidity and mortality.
- Protection of susceptible skin in patients where repetitive, rubbing motion, due to an underlying neurological or other medical condition can break down the skin.
- The ease of use for patients and carers, combined with a familiarity with the type of products in older patients or those with cognitive impairment may lead to greater compliance with pressure ulcer preventative measures.
- The products can be used in the home, primary or secondary care settings, enabling easy transition between these for the patient.

The benefits to the healthcare system claimed by the sponsor are:

- The ease-of-use and practicality of the Parafricta garments imply that this technology may be implemented easily in a community setting and could be used as a long term care strategy to improve patients' quality of life.
- Prevention of pressure ulcer formation and reduced pressure ulcer incidence would reduce the length of stay in the hospital setting and may allow a patient to be transferred to a lower cost community setting. Hospital acquired pressure ulcers result in lengthened hospital stays and increased patient complications.
- Reduction in NHS costs including but not limited to:
  - quicker return of patients to the community or community long-term care
  - reduced pressure ulcer incidence resulting in reduced costs of nursing care dressings and rehabilitation
  - re-usable nature of garments.

1.4 Relevant diseases and conditions

The Parafricta bootees and undergarments are intended to reduce friction and shear, specifically in people who have, or are at risk of having pressure ulcers or for people with frail skin or who have medical conditions where skin frailty is a primary factor.

Pressure ulcers

Pressure ulcers (also known as decubitus ulcers or pressure sores) are areas of localised skin damage caused by a number of intrinsic and extrinsic factors. Contributing extrinsic factors include pressure, friction, shear and moisture.

They most commonly develop on skin covering bony prominences such as the sacrum, heels, shoulders and hips. Pressure ulcers affect just under half a million people in the UK who develop at least one pressure ulcer in any given year. These are usually people with underlying health conditions.
Around 1 in 20 people who are admitted to hospital with an acute (sudden) illness will develop a pressure ulcer. People at high risk of developing pressure ulcers include those who:

- had a previous or current heel ulcer and therefore have a reduced tissue tolerance.
- have diabetes and may have peripheral neuropathy and numbness.
- had a stroke and have limited ability to move and neuropathy changes.
- have paralysis which may lead to insensibility and atrophy and skin thinning.
- have a hip fracture and may have shearing injuries from trying to prevent sliding down the bed.
- have dementia or cognitive impairment which can lead to a risk of rubbing injuries.
- have peripheral vascular disease which decreases vascular supply and reduces tolerance of mechanical forces.
- have leg spasms/Parkinson's/tremors/agitation any of which which may mean rubbing on the bed surfaces.
- have leg oedema which can compromise capillary flow, and reduced tissue tolerance.
- frequently slide down bed or chair or have poor posture in the chair or bed which leads to a risk of rubbing injury.

In the UK, chronic wounds represent a significant burden to patients and the NHS. Some 200,000 patients in the UK have a chronic wound. This includes leg ulcers, foot ulcers, and pressure ulcers.

Skin frailty

Paediatric and older patients may have skin frailty. Their thinner skin is likely to sustain injury more easily and take longer to heal. Both paediatric and older patients with significantly limited mobility, risk of nutritional deficiency, an inability to reposition, a neurological condition or significant cognitive impairment are at increased risk. Maintenance of functional areas relating to nutrition, mobility, cognition, fall prevention, pain management and continence, is integral to the management of skin integrity.

Epidermolysis bullosa is an inherited connective tissue disease causing blisters in the skin and mucosal membranes. It is relatively rare, with an estimated one in every 17,000 children born in the UK affected. There are currently an estimated 5,000 people living with the condition in the UK.

1.5 Current management

Current options for skin frailty and pressure ulcer prevention and management focus on the reduction or redistribution of pressure and include:

- dynamic or static high-specification pressure-relieving or pressure-redistributing beds, mattresses, overlays or cushions
- sheepskin: numerous products, shapes and sizes available
- pressure-relieving bootees: numerous shapes and sizes available
- silicone gel pads.

Pressure ulcer management

Pressure ulcer management (NICE clinical guideline 29), is being updated and NICE has published a draft guideline for consultation. The draft updated guideline recommends that when a person presents with, or is at increased risk of developing a pressure ulcer an initial risk assessment should be performed in first episode of care (within 6 hours) by a registered healthcare

professional. Risk should be assessed and documented taking into consideration all the recognised risk factors including pressure, shear and friction; the level of mobility; sensory impairment; continence; level of consciousness; acute, chronic and terminal illness; co-morbidity; pain; location and management interventions; posture; previous pressure damage; extremes of age; nutrition and dehydration and moisture to the skin. Risk should be reassessed on an on-going basis and in particular if the person's circumstances change.

CG29 recommends that once risk has been assessed, mobilising, positioning and repositioning interventions (including those in beds, chairs, and wheelchair users) should be considered for people who have, or are at risk of developing pressure ulcers, to prevent damage or further skin damage from occurring. Pressure-relieving/pressure-reducing devices should be chosen by a registered healthcare professional on the basis of risk assessment. All vulnerable people should receive, as a minimum provision, a high specification foam mattress (pressure relieving), and any ulcer should be closely observed for deterioration. As a minimum provision, people with a grade 3-4 pressure ulcer should receive a bed with an alternating pressure mattress or high specification foam mattress with an alternating pressure overlay, or a sophisticated continuous low pressure system.

2 Reasons for developing guidance on Parafricta bootees and undergarments to reduce skin breakdown in people with frail skin or at risk of pressure ulcers

The Committee heard from experts that if the claims are realised, then this technology would be beneficial to patients. Specifically, the Committee considered that the use of Parafricta bootees and undergarments may result in a reduced incidence of skin breakdown and pressure ulcer incidence.

The Committee was advised that the people who would be likely to get the most benefit from the use of Parafricta bootees and undergarments are those who have or may develop pressure ulcers and are able to move about.

The Committee was advised that Parafricta bootees and undergarments may also be particularly beneficial for bedbound patients who move about in bed in an involuntary way and for those who have repetitive body movements. This could include those who have musculoskeletal and neurological medical conditions.

The Committee was advised that it is likely that Parafricta devices will be used in addition to and in conjunction with current practice for management of skin frailty and pressure ulcer prevention. Nonetheless, it concluded that it is plausible that overall cost savings might be realised through a reduction in the incidence of pressure ulcers and the considerable costs associated with their treatment.

3 Statement of the decision problem

	Scope issued by NICE

Population	People (adults or children of any age) in a community or hospital setting who:
	• have a grade 1 or 2 pressure ulcer and are at risk of progressing to grade 3 or 4 pressure ulcer
	• 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
	  ○ have impaired sensation and are at risk of skin breakdown or damage
	  ○ have peripheral arterial disease, who have a very high risk of developing ulcers
	• have medical conditions where skin frailty is a primary factor and where friction and shear could cause skin damage.

Intervention	In all settings:
	• Pressure-reducing devices used in standard NHS clinical practice, primarily:
	  – dynamic or static high-specification pressure-relieving mattresses and overlays
	  or
	  – dynamic or static high-specification pressure-redistributing mattresses and overlays
	but may also include:
	  – dynamic or static high-specification pressure-relieving beds
	  or
	  – dynamic or static high-specification pressure-redistributing beds
	  or
	  – silicone gel pads.
	AND
	• Parafricta bootees (slip on and Velcro fastening)* specifically used to protect the heel and ankle
	• Parafricta undergarments (slip-on-boxer, slip-on brief, and undergarment with Velcro closure)* specifically used to protect the sacrum, buttocks and hips.
	*The Parafricta bootees and undergarments are intended to be used as an adjunct to other pressure-reducing devices currently used in standard NHS clinical practice.

Comparator(s)	In all settings, and used without Parafricta: • pressure-reducing devices used in standard NHS clinical practice (as listed in the Interventions)

	or • pressure-reducing devices plus sheepskin or • pressure-reducing devices plus pressure-relieving bootees.
Outcomes	Relevant outcome measures include: • incidence of grade 1 or 2 pressure ulcers progressing to grade 3 or 4 • incidence of developing pressure ulcers • incidence of skin breakdown • severity of pressure ulcers • length of hospital stay • time-to-healing for those who present with an existing pressure ulcer • patient compliance with pressure ulcer management interventions • patient comfort: including ability to move and self-reposition in bed • quality of life • morbidity • device-related adverse events.
Cost analysis	The bootees and undergarments are primarily intended to be used as an adjunct to the current pressure-reducing devices. The cost analysis should compare the costs and consequences of the use of pressure-reducing devices with and without the use of Parafricta garments in all settings. Pressure-reducing devices in standard NHS clinical practice are detailed in the Interventions section. Parafricta products are re-usable, and therefore costs of care and laundry of the products should be considered. Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• people with restricted mobility who may be bedbound • people who may have skin damage due to musculoskeletal or neurological conditions where repetitive motion is present.
Special considerations, including those related to equality	It should be noted that people with chronic wounds, including pressure ulcers, may be protected under the Equality Act 2010. The device may have particular advantages for people who have chronic wounds and may be classed as having a disability under the 2010 Equality Act. Other groups covered by the Equality Act are people with diabetes who may have foot ulcers as a result and people who have spinal injuries and may have pressure ulcers. This device would not restrict the access for treatment for these groups of people.

Special considerations, specifically related to equality issues		
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
	* Delete as appropriate, if yes please provide further details here: n/a	

4 Related NICE guidance

Published

- Mega Soft Patient Return Electrode for use during monopolar electrosurgery. NICE Medical Technologies Guidance MTG11 (2012). Available from: http://guidance.nice.org.uk/MTG11 Date for review: TBC
- Prevention and treatment of surgical site infection NICE Clinical Guideline CG74 (2008). Available from: http://guidance.nice.org.uk/CG74. Date for review: August 2014
- Metastatic spinal cord compression: diagnosis and management of adults at risk of and with metastatic spinal cord compression NICE Clinical Guideline CG75 (2008). Available from: http://guidance.nice.org.uk/CG75 Date for review: Reviewed August 2012 and decided not to renew at this stage. The guideline should cross-refer to the new TA: Bone metastases from solid tumours- denosumab published in September 2012 *Section 1.6.2 covers the management of pressure ulcers*
- Diabetic foot - inpatient management of people with diabetic foot ulcers and infection NICE Clinical Guideline CG119 (2011). Available from: http://guidance.nice.org.uk/CG119. Date for review: TBC
- Type 2 diabetes: prevention and management of foot problems NICE Clinical Guideline CG10 (2004) Available from: http://guidance.nice.org.uk/CG10 Date for review: January 2014

- Pressure ulcers: The management of pressure ulcers in primary and secondary care NICE Clinical Guideline CG29 (2005) Available from: http://guidance.nice.org.uk/CG29 Date for review: reviewed May 2011 and decision made to update
- Pressure relieving devices: the use of pressure relieving devices for the prevention of pressure ulcers in primary and secondary care NICE Clinical Guideline CG7 (2003) Available from: http://guidance.nice.org.uk/CG7 Date for review: Reviewed May 2011 and decision made to update and amalgamate with CG29
- Management of multiple sclerosis in primary and secondary care NICE Clinical Guideline CG8 (2003) Available from: http://www.nice.org.uk/CG8 Date for review: Update currently underway and expected to be published in October 2014 *Section 1.7.19 addresses the management of pressure ulcers*
- Negative pressure wound therapy for the open abdomen NICE Interventional Procedure Guidance IPG322 (2009). Available from: http://guidance.nice.org.uk/IPG322 Date for review; TBC
- MoorLDI2 Burns Imager a laser Doppler blood flow imager for the assessment of burn wounds NICE Medical Technologies Guidance MTG2 (2011). Available from: http://guidance.nice.org.uk/MTG2 Date for review: TBC
- MIST Therapy system for the promotion of wound healing in chronic and acute wounds (MTG5) NICE Medical Technologies Guidance MTG5 (2011). Available from: http://guidance.nice.org.uk/MTG5 Date for review: TBC
- The PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites NICE Medical Technologies Guidance MTG9 (2012). Available from: http://publications.nice.org.uk/the-pleurx-peritoneal-catheter-drainage-system-for-vacuum-assisted-drainage-of-treatment-resistant-mtg9 Date for review: TBC

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Pressure ulcers: prevention and management of pressure ulcers: NICE clinical guideline (publication expected May 2014) This guideline will update and replace the following NICE guidelines:
  - Pressure ulcers. NICE clinical guideline 29 (2005). Available from www.nice.org.uk/guidance/CG29
  - Pressure ulcer prevention. NICE clinical guideline 7 (2003). Available from www.nice.org.uk/guidance/CG7
  - Multiple sclerosis. NICE clinical guideline 8 (2003). Available from www.nice.org.uk/guidance/CG8 (recommendations on pressure ulcers only)

  Two of the key clinical issues that will be covered are the prevention and management of pressure ulcers. This includes looking at pressure-relieving devices including mattresses, cushions, sheepskins, overlays, beds, limb protectors and seating. The Parafricta products may fall within scope..

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of Surgeons in Primary Care
- British Association of Dermatologists
- British Dermatological Nursing Group (BDNG)
- British Geriatrics Society
- British Medical Ultrasound Society
- British Society for Dermatological Surgery
- European Wound Management Association

- Primary Care Dermatology Society (PCDS)
- Primary Care Diabetes Society
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Society of Chiropodists & Podiatrists (Feet for Life)
- Tissue Viability Society
- Vascular Society Of Great Britain and Ireland
- Wound Alliance UK

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of Surgeons in Primary Care
- British Dermatological Nursing Group (BDNG)
- British Geriatrics Society
- British Medical Ultrasound Society
- European Wound Management Association
- Primary Care Dermatology Society (PCDS)
- Primary Care Diabetes Society
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Society of Chiropodists & Podiatrists (Feet for Life)
- Tissue Viability Society
- Vascular Society Of Great Britain and Ireland
- Wound Alliance UK

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- British Skin Foundation
- Disability Rights UK
- Disabled Living Foundation
- Ethnic Health Foundation
- European Pressure Ulcer Advisory Panel
- Independent Age
- James Lind Alliance Pressure Ulcer Priority Setting Partnership
- Leg Ulcer Forum
- Limbless Association
- Lindsay Leg Club Foundation
- Multiple Sclerosis Resource Centre
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- Muscular Dystrophy Campaign
- Posture and Mobility Group
- Shine
- Spinal Injuries Association