NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Debrisoft for the debridement of acute and chronic wounds

1 Technology

1.1 Description of the technology

The Debrisoft (Activa Healthcare Ltd.) is a single-use debridement pad for use by nurses and other healthcare professionals on adults and children to remove devitalised tissue, debris, and hyperkeratotic skin caused by chronic and acute wounds. Debrisoft is used to ensure the wound bed is not obscured, aiding full assessment and any further treatment if required. Expert advisers state that Debrisoft should be used only after a registered healthcare professional has made a clinical assessment.

Debrisoft is a sterile, single-use pad (10cmx10cm) of monofilament polyester fibres with a reverse side of polyacrylate. The monofilament fibres are cut with angled tips designed to penetrate irregularly shaped areas and remove devitalised skin and wound debris. The pad is moistened with sterile water or saline (with excess shaken off), and is then folded and wiped across the wound with an appropriate amount of pressure. Cellular debris, slough (necrotic tissue), exudate and hyperkeratotic tissues become integrated into the monofilaments and are therefore removed from the procedure site. Debrisoft is intended for use without analgesia, and the process takes, on average, 2-4 minutes. The sponsor recommends that emollients be washed from the skin before treatment with the device. A new Debrisoft pad is required for each separate area of skin being treated. For large areas, more than one pad may be required. Debrisoft is provided in boxes of 5 pieces, and after use is treated as clinical waste for disposal.

1.2 Regulatory status

The Debrisoft received a CE mark in December 2009 for use in people with devitalised tissue such as necrotic tissue and debris and hyperkeratotic skin caused by certain chronic and acute wounds.

1.3 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Reduction in pain associated with debridement with no analgesia required in most cases
- Improved acceptability to patients with reduced fear and anxiety associated with treatment
- Faster treatment and healing with reduced frequency and total episodes of care
- Reduced risks of trauma to healthy tissue, and of bleeding

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

- Reduced time and resources associated with debridement and reduced overall time to healing
- Use by nurses and other healthcare professionals in the community leading to lower costs and shorter waiting times for treatment.
- More effective debridement facilitating initial assessment with the possibility of reduced referrals, hospital administration and inappropriate treatment through misdiagnosis
- Improved patient concordance with reduced costs of analgesia often required with other forms of debridement
- Avoidance of on-going costs relating to specialist methods of debridement and treatment that require additional consumables.

1.4 Relevant diseases and conditions

The Debrisoft is intended for use on adults and children with devitalised tissue such as necrotic tissue, debris and hyperkeratotic skin caused by chronic and acute wounds. The types of chronic wounds that may be relevant include

pressure ulcers, leg ulcers, diabetic foot ulcers and lymphoedema. The types of acute wounds that may be relevant include haematomas, surgical dehiscences and burns.

Chronic wounds

In the UK in 2008, approximately 200,000 people had chronic wounds. These include pressure, leg, and foot ulcers. 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 an underlying health conditions. Around 1 in 20 people who are admitted to hospital with an acute illness will develop a pressure ulcer. Chronic ulceration is more prevalent in people aged over 65.

Leg ulcers affect 1 in 500 people although this rises sharply, with age, to 1 in 50 in those over the age of 80. In the UK, the annual incidence of foot ulcers among people with diabetes is 2-5% with the annual need for amputation being 0.25-1.8%. Approximately 10% of all leg ulcers are caused by arterial insufficiency.

Lymphoedema is a chronic condition which is characterised by oedema occurring in 1 in 10,000 people in the UK. Primary lymphoedema is an inherited condition, is more prevalent in women and mainly affects the legs whereas secondary lymphoedema or chronic oedema may be caused by an injury to the lymph system or by venous disease. This affects approximately 100,000 people in total in the UK. Skin and tissue problems in lymphoedema include hyperkeratosis (thickened scaly areas).

Acute and subacute wounds

Acute wounds can be surgical or traumatic. Acute wounds require management to prevent infection and promote healing.

Subacute wounds are those that have reached a stage of healing characterized by new growth of connective tissue and capillaries, usually between the 4th and 21st day of healing.

Burn wounds cause an estimated hospital admission rate of 0.29 per 1,000 cases of burn or smoke inhalation. In the UK, it is estimated that each year about 250,000 people with burn injuries present to primary care.

Dehiscences are characterised by the opening of surgical wounds. Mortality rates of between 14% and 50% have been reported with surgical wound dehiscence.

Approximately 4.2 million surgical procedures are carried out each year in England alone. Wound haematomas are a relatively common complication of surgical procedures. Haematomas delay healing in acute traumatic wounds and can result in infection as a complication.

1.5 Current management

Debridement is the removal of dead, damaged tissue or haematoma from the wound, helping it to repair. This process occurs naturally (autolytic debridement) but can take time. Several techniques are used to debride wounds, the choice of which varies by wound type, and include:

- Surgical/sharp debridement
  - Scalpel
- Mechanical debridement
  - Gauze swabs
  - Pressurised wound irrigation (for small wounds)
  - Whirlpool – using jets of water (large wounds)
- Autolytic debridement
  - Dressings to support wound healing – moisture retention dressing.
  - Hydrogels and compression bandages
- Biosurgical debridement
  - Larvae
- Enzymatic debridement
  - proteolytics, fibrinolytics, collagenase.

Debridement can be carried out under general or local anaesthetic, and with or without analgesia depending on the degree of wound pain, site size and severity of the wound as well as the patient's needs.

Chronic wounds

Debridement is part of standard care for chronic wounds. Standard care for chronic, non-healing wounds such as venous leg ulcers involves, in addition, the use of advanced wound dressings and the use of antibiotics to treat infection. NICE Clinical Guideline 29 'Pressure ulcer management' states that standard practice in the management of chronic wounds should include wound debridement to remove dead tissue and that clinicians should recognise the positive potential benefit of debridement in the management of pressure ulcers. NHS Choices includes the technique of debridement in the treatment pathway for pressure ulcers and lists methods including mechanical, surgical, autolytic, chemical/hydrogels and bio-surgical/larvae therapy debridement techniques.

The NICE clinical guideline 119 'Diabetic foot problems', recommends that diabetic foot ulcers are managed by a multidisciplinary foot care team and new ulcers are assessed by an appropriately trained health professional within 24 hours of them developing. Choice of dressings and therapy is dependent on the site and size of the ulcer, patient preference, clinical circumstances and experience as well as dressing costs. For hospital inpatients, the NICE clinical guideline 119 'Diabetic foot problems', states that an assessment of the foot should be carried out to determine the need for specialist wound care including debridement. The guideline states that debridement should be performed only by healthcare professionals from the multidisciplinary foot care team, using the technique that best matches their specialist expertise, clinical experience, patient preference, and the site of the ulcer.

Acute and subacute wounds

The clinical pathway for people with burns or dehisced wounds is not well-defined and varies by wound type. All types of burns may need medical attention. Deep partial-thickness and full-thickness burns may require wound

care. Treatment for dehisced wounds may include antibiotics, wound packing, and negative pressure therapy.

Haematomas with overlying necrotic skin can be treated conservatively using autolytic, larvae or honey debridement. If the haematoma is very large, surgical debridement and treatment may be required dependent on depth, severity, size, position and patient related factors.

2 Reasons for developing guidance on Debrisoft for the debridement of acute and chronic wounds

The Committee was advised that, although current debridement practice is not well-standardised, it is likely that community healthcare professionals will use saline to clean, and then may use gauze or hydrogel to debride, a wound. The Committee noted that it is possible that both gauze and hydrogel could be used for the same wound (gauze to clean, hydrogel to debride). It was advised that guidance on Debrisoft would be valuable in promoting the use of debridement in the NHS.

The Committee was advised that Debrisoft may be more effective at debridement than the current practice of irrigating wounds with saline or gentle cleansing with gauze or using hydrogel or other autolytic dressing.

The Committee heard from experts that cleansing with gauze may be painful and concluded that Debrisoft may be less painful to patients.

The Committee considered that the use of Debrisoft may result in a reduced time-to-healing.

The Committee considered that the use of Debrisoft may result in a reduction in overall wound dressings used.

The Committee considered that an improvement in clinical outcomes associated with the use of Debrisoft for the debridement of acute and chronic wounds may contribute to overall cost savings as compared with current

practice. The cost savings may result from a reduction in the number, length and frequency of nurse visits.

3 Statement of the decision problem

	Scope issued by NICE

Population	People (adults or children of any age) requiring debridement of an acute or chronic wound by a healthcare professional (nurse) in a community-based setting. The chronic or acute wounds could be open (non-intact skin) or closed (intact skin). Wound types are likely to include:
	• Chronic
	  ○ lymphoedema
	  ○ pressure ulcers
	  ○ leg ulcers
	  ○ diabetic foot ulcers
	• Acute (and subacute) – surgical or trauma
	  ○ burns
	  ○ dehisced
	  ○ haematomas (in acute wounds)

Intervention	Debrisoft single-use pad.
Comparator(s)	The comparator is likely to vary by wound type and is expected to include irrigating the wound with saline and : - using hydrogel or other autolytic dressing or - cleansing with gauze (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • quality of life • pain and discomfort for the patient when debriding the wound • wound malodour • time-to-complete debridement (not necessarily complete healing) • time-to-healing • wound infection/cellulitis • the number of healthcare professional (nurse) visits for each patient • the frequency of healthcare professional (nurse) visits for each patient • the duration of each visit by the healthcare professional (nurse) for each patient • the number of debridements required • the number of dressings required to dress the wound • the type of dressings required to dress the wound • the need to refer to a Tissue Viability Nurse or Hospital specialist clinic • the need to escalate to other debridement methods. E.g.

	surgical debridement • device-related adverse events including non-selective trauma to healthy surrounding tissue or bleeding.
Cost analysis	Comparator(s): Complete debridement of all the different types of wound (including open and closed chronic and acute wounds) should be considered. The individual comparators are likely to vary by wound type and are expected to include irrigating the wound with saline and - using hydrogel or other autolytic dressing or - cleansing with gauze 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 (adults or children - with no age limit) with closed acute or chronic wounds where the skin is intact (including people with lymphoedema and hyperkeratotic skin). • People (adults or children - with no age limit) with open acute or chronic wounds where the skin is non-intact (including haematoma).
Special considerations, including issues related to equality	It should be noted that people with chronic wounds 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 and 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.

4 Related NICE guidance

Published

- 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
- 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
- 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

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). The scope includes debridement of pressure wounds

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 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

5.2 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
- Burned Children's Club
- Changing Faces
- Children's Burn Trust (CBT)
- Counsel and Care
- Dan's Fund for Burns
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Disability Rights UK
- Disabled Living Foundation
- Eczema Voice
- Ethnic Health Foundation
- Foot in Diabetes UK
- Insulin Dependent Diabetes Trust
- Let's Face It

- Limbless Association
- Lindsay Leg Club Foundation
- Lymphoedema support network
- Multiple Sclerosis Resource Centre
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- Muscular Dystrophy Campaign
- Psoriasis and Psoriatic Arthritis Alliance (PAPAA)
- Psoriasis Association
- Shine
- Skin Care Campaign
- Spinal Injuries Association
- Surya Foundation
- Talkeczema
- The National Eczema Society