NICE National Institute for Health and Care Excellence

NICE guidance

The Debrisoft monofilament debridement pad for use in acute or chronic wounds

Medical technologies guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 The case for adopting the Debrisoft monofilament debridement pad as part of the management of acute or chronic wounds in the community is supported by the evidence. The available evidence is limited, but the likely benefits of using the Debrisoft pad on appropriate wounds are that they will be fully debrided more quickly, with fewer nurse visits needed, compared with other debridement methods. In addition, the Debrisoft pad is convenient and easy to use, and is well tolerated by patients. Debridement is an important component of standard woundcare management as described in the NICE guidelines on pressure ulcers and diabetic foot problems. **[2019]**

1.2 The Debrisoft pad is indicated for adults and children with acute or chronic wounds. The available evidence is mainly in adults with chronic wounds needing debridement in the community. The data show that the device is particularly effective for chronic sloughy wounds and hyperkeratotic skin around acute or chronic wounds.

1.3 The Debrisoft pad is estimated to be cost saving for complete debridement compared with other debridement methods. When compared with hydrogel, gauze and bagged larvae, cost savings per patient (per complete debridement) are estimated to be £99, £154 and £373 respectively in a community clinic, and £213, £292 and £277 respectively in the home. **[2019]**

2 The technology

Description of the technology

2.1 The Debrisoft range (L&R Medical UK) are sterile and single-use monofilament debridement devices intended for nurses and other healthcare professionals to use on adults and children to remove devitalised tissue, debris, and hyperkeratotic skin around acute or chronic wounds. They are made 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. There are 2 sizes of pad (10 cm × 10 cm and 13 cm × 20 cm, both with a hand pocket to facilitate handling) and a version with a handle (Debrisoft Lolly). **[2019]**

2.2 The Debrisoft pad is moistened with tap water, sterile water or saline, folded and then, using the soft fleecy side, wiped across the wound with gentle pressure. Cellular debris, slough tissue, exudate and hyperkeratotic tissues become integrated into the monofilaments and are removed from the wound site. The Debrisoft pad is intended for use without analgesia, and the process takes, on average, 2 to 4 minutes. A new pad is normally needed for each separate wound being treated. For large areas, more than 1 pad may be needed.

2.3 The cost of 1 Debrisoft monofilament debridement pad stated in the sponsor's submission in August 2013 was £6.19 and is currently £6.27 (both excluding VAT).

2.4 The claimed benefits of the Debrisoft pad in the case for adoption presented 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
- 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 ongoing costs relating to specialist methods of debridement and treatment that require additional consumables.

Current management

2.5 Debridement is the removal of dead, damaged tissue or haematoma from a wound. Several techniques are used for debridement, depending on the nature of the wound. In the community these are likely to include mechanical, autolytic and biosurgical techniques. Debridement can be carried out with or without analgesia depending on the degree of wound pain, the site, size and severity of the wound as well as the patient's preference.

2.6 The NICE guideline on pressure ulcers states that standard practice in the management of chronic wounds includes wound debridement to remove dead tissue, and that clinicians should recognise the potential benefit of debridement in the management of pressure ulcers. NICE includes the technique of debridement in the NICE Pathway on pressure ulcers. **[2019]**

2.7 The NICE guideline on diabetic foot problems recommends that diabetic foot ulcers can be managed using debridement. The guideline states that debridement should be performed only by healthcare professionals from a multidisciplinary foot care team, using the technique that best matches their

specialist expertise, clinical experience, patient preference, and the site of the ulcer. **[2019]**

2.8 The clinical pathway for people with burns or with surgical wounds that have ruptured (dehisced) is not well defined and varies by wound type. Treatment for dehisced wounds may include antibiotics, wound packing, and negative pressure wound 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 needed dependent on depth, severity, size, position and patient-related factors.

3 Clinical evidence

Summary of clinical evidence

3.1 Full details of all clinical outcomes considered by the Committee are available in the assessment report overview.

3.2 The key clinical outcomes for the Debrisoft monofilament debridement pad presented in the decision problem were:

- pain and discomfort for the patient when debriding the wound
- wound malodour
- time to complete debridement
- time to healing
- wound infection/cellulitis
- the number, frequency and duration of healthcare professional (nurse) visits for each patient
- the number of debridements needed
- device-related adverse events, including non-selective trauma to healthy surrounding tissue or bleeding.

3.3 The clinical evidence for the Debrisoft pad was based on 15 multiple-patient case-series reports (5 peer-reviewed papers and 10 posters), some of which included retrospective comparators. There were no randomised controlled trials. The External Assessment Centre considered that 7 studies (Bahr et al. 2011; Callaghan and Stephen-Haynes, 2012; Collarte et al. 2011; Johnson et al. 2012a; Mustafi et al. 2011; Pietroletti et al. 2012; Wiser et al. 2012) were directly relevant to the scope because they included appropriate comparators and outcomes. Two of the papers (Bahr et al. 2011; Mustafi et al. 2011) presented results from the same study.

Multiple patient case-series: peer-reviewed papers

3.4 Bahr et al. (2011) and Mustafi et al. (2011) compared the overall mean time of each debridement session, using the Debrisoft pad, with hydrogel, gauze and surgical debridement in 60 patients. In minutes, this was 2.51 (SD±0.57) for Debrisoft, 7 (±2.08) for hydrogel, 5 (±1.60) for gauze and 9 (±2.64) for surgical debridement. Complete debridement was achieved in 77% (n=44) of patients using the Debrisoft pad in 12 days compared with an estimate taken from the literature of approximately 20 days for enzymes or hydrogel. Using a 6-point scale (1=excellent to 6=inadequate), Debrisoft users rated its debridement efficacy as 'very good', giving a mean score of 1.98 (±0.68) compared with hydrogel, which scored 2.54 (±0.72). The convenience and ease of use of the Debrisoft pad was rated 'very good' by its users, with a mean score of 2.29 (±0.57) on the 6-point scale. Wet gauze was rated similarly with a mean score of 2.49 (±0.67). When using the Debrisoft pad, there was a significant improvement in wound bed condition after 3 debridement sessions. After 1 session, 60% of wounds (n=34) were categorised as covered in slough with some necrotic tissue, after 3 sessions this was 47% (n=27). After 1 session 28% of wounds (n=16) were categorised as covered in slough with no necrotic tissue, after 3 sessions this was 25% (n=14). After 1 session 12% of wounds (n=7) were clean with less than 20% slough, after 3 sessions this was 7% (n=4). Twenty-one per cent (n=12) of wounds had re-epithelialised. Debridement was effective in 93.4% (142/152) of the sessions. During the debridement procedure 45% (n=26) of patients reported that they experienced no pain, 50.4% (n=29) reported slight discomfort of short duration (mean 2 minutes) and 4.6% (n=2) reported moderate pain of short duration (mean 2.4 minutes). No side effects after the procedure were reported by 56 out of 57 patients. No serious adverse events or adverse events were reported. Clinicians reported that the Debrisoft pad removed debris, slough, dried exudate and crusts efficiently, without damaging the fragile skin surrounding the wound. Photographic analysis confirmed this.

3.5 Gray et al. (2011) described a case series of 18 patients that evaluated which types of slough and necrotic tissue benefit most from debridement with the Debrisoft pad. One patient was unable to tolerate the use of the pad. Results were reported for 10 patients only. Two patients had hyperkeratotic skin removed on their lower limb in less than 2 minutes. One patient's hyperkeratotic skin was not removed by the Debrisoft pad, but it was thought that this was because an

emollient was applied before the treatment. Two patients had their wound beds cleared of any haematoma after it had been debrided for less than 5 minutes. One patient had most (not specified how much) of their haematoma cleared from the wound bed. Two patients with pressure wounds on the heel were reported as having partially successful debridement (not clear how successful). Sloughy leg ulcers in 2 patients were fully debrided. The authors noted that when dry, black necrosis or slough had adhered to the wound bed, the Debrisoft pad did not remove the devitalised tissue.

3.6 Hammerle et al. (2011) described a case series of 11 patients with chronic wounds from 2 hospitals. The Debrisoft pad was able to remove most of the coatings in exudating, seropurulent wounds with highly viscous yellow slough (indicating local infection) after a single use. Most of the material removed by debridement became attached to the pad. In dry wounds with serocrusts between the new vital granulation and epithelial tissue, the Debrisoft pad was able to remove the crusts without affecting the new healthy tissue. In wounds with necrotic layers, hyperkeratotic debris and crusts of dried exudate, the Debrisoft pad removed the necrotic layers after a single use and revealed the skin of the lower extremity, showing an almost normal epidermis. For both types of wound, the Debrisoft pad was able to debride without affecting the new healthy tissue, which was undisturbed by the debridement process.

3.7 Johnson et al. (2012a) described a 2-centre observational study that compared the effectiveness of the Debrisoft pad with other non-specified debridement methods. Ten patients were recruited from each centre. Although it was not stated explicitly, it appears from the results that each wound was treated once using the Debrisoft pad. Patients found the treatment very acceptable with minimal pain reported in 95% of cases. The reported time to debridement was 2–4 minutes for 10 patients, 5–7 minutes for 5 patients and more than 7 minutes for 5 patients. Skin condition after Debrisoft pad use compared with a previous hyperkeratosis method was rated for 8 patients and was 'much better' for 6 patients, 'good' for 1 patient and 'very good' for 1 patient. Debridement performance compared with a previous method was rated for 16 patients by the clinician and was 'much better' for 8 patients, 'good' for 5 and 'very good' for 3.

3.8 Stephen-Haynes and Callaghan (2012) evaluated the use of the Debrisoft pad by 40 tissue viability nurses, over a 12-week period, on a wound or hyperkeratosis.

The Debrisoft pad was used for wound debridement by 25 nurses (62.5%), for hyperkeratosis by 4 nurses (10%), and for both by 11 nurses (27.5%). Thirty-eight of the nurses (95%) said that patients' skin condition improved, whereas 2 (5%) said that it remained the same. Thirty-two of the nurses (80%) reported a positive impact on the wound bed using visual assessment. Thirty-four nurses (85%) reported that after debridement, there was clearer visibility of the wound bed and surrounding skin because of the removal of debris, slough or hyperkeratosis, so they were able to identify clearer wound management objectives. Six out of 40 nurses (15%) said there was no improvement. The time taken to carry out debridement using the Debrisoft pad was 0–2 minutes in 8 patients (20%); 3–5 minutes in 21 patients (52.5%) and 6–10 minutes in 9 patients (22.5%). The overall performance of the Debrisoft pad was rated as 'very good' by 24 nurses (60%), 'good' by 10 nurses (25%), 'fairly good' by 5 nurses (12.5%) and 'poor' by 1 nurse (2.5%).

Multiple patient case-series: posters

3.9 Albas (2012) evaluated the Debrisoft pad for 10 patients with trauma wounds and bites. Debridement was considered effective in all patients because visible debris and slough were successfully removed. A mean of 2.1 sessions (SD±0.83; range: 1–3) was needed to obtain a clean wound bed. In all sessions, the product remained intact. The mean time for the debridement sessions was 2.57 minutes (SD±0.04; range 2–4). Patients reported slight discomfort for a short duration (2 minutes on average) in 35% of cases and no discomfort in 65% of cases. No secondary infections were reported.

3.10 Callaghan and Stephen-Haynes (2012) described a case series of 12 patients with pressure ulcers. The time to achieve debridement was 0–5 minutes in all 12 patients. Four patients had pain during the procedure (visual analogue scale [VAS]: 1, 1, 6, 4) but the first 3 of these patients had pain before treatment started (VAS: 1, 1, 7). No patients reported pain after treatment. There was improved visualisation of the wound bed in 92% (11/12) of the patients. Treatment using the Debrisoft pad reduced wound care visits in 92% (11/12) of the patients. The treatment helped assess the category of pressure ulcer in all 12 patients.

3.11 Collarte et al. (2011) evaluated the use of the Debrisoft pad in 10 patients and

reported that it was easy to use and removed devitalised tissue and hyperkeratosis more quickly compared with standard treatment. The time to treat was decreased and patients found the treatment to be comfortable. One patient had a venous leg ulcer debrided in 4 minutes using the Debrisoft pad, with no reported pain or discomfort. Previously nurses had attempted to debride the wound with autolytic therapy and larvae, but with limited success.

3.12 Dam (2012) evaluated the Debrisoft pad in 29 patients with chronic wounds. On average, fibrin was reduced by 30%. It was reported that thin and soft layers of fibrin were easier to remove than thick fibrin and necrotic tissue. The Debrisoft pad was not able to remove fibrin that had firmly adhered to the wound bed. Topical analgesia was used in 11 patients; 8 patients reported no change in pain level and 10 patients reported increased pain during debridement. Keratosis was present in 21 patients and this was removed by the Debrisoft pad in all 21 patients.

3.13 Johnson (2012b) described a case series in which the Debrisoft pad facilitated healing in all 10 patients. It was stated that pain scores remained low during debridement, with most patients scoring the same before, during and after the procedure. The average debridement time was 4 minutes (range 2–10). The time to complete healing was recorded as between 2 weeks for 2 patients with venous leg ulcers and 6 weeks for 2 patients with mixed aetiology. The wound of 1 patient treated before a below knee amputation healed with no complications but it was not stated how long this took. The wounds of 2 other patients did not heal before the end of the 12 weeks and 1 patient was lost to follow-up.

3.14 Pietroletti et al. (2012) assessed the efficacy of the Debrisoft pad in a case series of 27 patients. The data were retrospectively compared with a group of 25 patients who had used an autolytic debridement method of either hydrogel or enzymes. The wound condition in both groups was wound bed coated with fibrin and slough or skin around the wound with keratosis and/or exudate. The maximum area of the wounds was 60 cm^2. Results showed that 92% of patients had their wound debrided after 1 application of the Debrisoft pad. This involved 1 visit, whereas 38.4% of patients had debrided wounds after 1 application of the autolytic or enzymatic debridement, which involved 2 visits. The author concluded that based on these results, autolytic debridement would need to be used 8 to 10 times to achieve the same results as the Debrisoft pad.

3.15 Rieke (2012) reported the results of an observational study of 25 patients in which the Debrisoft pad was used on diabetic foot ulcers. Debridement was effective in all of the sessions and visible debris, slough, hyperkeratosis and scabs were successfully removed. In 8 cases additional surgical debridement was performed to remove the thick callus at the edges. The mean time for each debridement session was 2.59 minutes (±SD 0.06). Eighteen of the 25 ulcers healed within 16 weeks (study end point), 2 needed surgery and 5 did not heal.

3.16 Skovgaard-Holm and Simonsens (2012) described a study of 10 patients that was completed by homecare nurses. Debridement using the Debrisoft pad was performed 3 times a week over a 2-week period. The efficacy rate of the Debrisoft pad was found to depend on the thickness and adherence of the slough and the thickness of the hyperkeratotic layer. Debridement reduced the area of thin slough by an average of 24% in 3 patients. In 6 patients, an adherence layer of slough was reduced by an average of 7%. The Debrisoft pad reduced a thick soft layer of slough by 10% in 1 patient. Three patients did not feel increased pain during treatment, but 3 experienced severe pain (VAS scores of 8, 7 and 6). The pain level decreased immediately after treatment to the level at the starting point. The nurses felt that 4 patients would have benefitted from local anaesthesia before treatment.

3.17 Wiser et al. (2012) retrospectively compared the debridement results using the Debrisoft pad in 15 patients with venous leg ulcers or diabetic foot ulcers with a sloughy wound bed with the results obtained with saline soaks used in a similar patient group. No quantitative results were reported. The Debrisoft pad was shown to deliver effective and fast debridement, but it was reported to be somewhat rigid when used on toes or cavity wounds. Patient-reported pain during the procedure was less than for those treated with saline soaks, especially for the patients with arterial ulcers. The slight discomfort reported with the Debrisoft pad seemed to be better tolerated than debridement using saline soaks. Use of the product did not cause damage to the fragile skin surrounding the wound.

Adverse events

3.18 No adverse event reports relating to the Debrisoft pad were reported in a search

of the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. The Medicines and Healthcare products Regulatory Agency (MHRA) has not received any reports of adverse events relating to the Debrisoft pad.

Committee considerations

3.19 The Committee noted that the clinical evidence base for the Debrisoft pad was limited to 15 studies with 10 of these coming from poster presentations. The Committee agreed with the External Assessment Centre's conclusions that there was a lack of good quality comparative evidence. The Committee recognised that the lack of this type of evidence is common in woundcare management, and it would encourage the collection of better quality comparative evidence to improve decision-making in the debridement of acute or chronic wounds.

3.20 The Committee considered that the studies provided evidence that the Debrisoft pad was safe to use for wound debridement and in some cases had equal or greater efficacy than the comparators. Using expert advice and the available evidence the Committee judged that the Debrisoft pad was likely to completely debride appropriate wounds more quickly than gauze and hydrogel. The Committee accepted that quicker debridement may give earlier visibility of the wound bed and therefore enable better management of the wound. In addition, the Committee considered that the Debrisoft pad was convenient and easy to use, and was well tolerated by patients.

3.21 The Committee considered that there was evidence of efficacy for the use of the Debrisoft pad on sloughy wounds with exudate and hyperkeratotic skin. It noted from the clinical evidence and expert advice that the Debrisoft pad may not be as effective on wounds in which black necrosis or slough had adhered to the wound bed. The Committee considered that little evidence was presented that was specific to use on acute wounds or to the treatment of children. The Committee concluded that appropriate wound selection is important for the use of the Debrisoft pad.

3.22 The Committee noted that NICE clinical guidelines support wound debridement, but that the clinical pathway may vary for different types of wounds. The

Committee accepted expert advice that hydrogel and larvae are the most appropriate comparators currently used in the community for the same type of wounds as the Debrisoft pad. The Committee considered that the role of gauze in clinical practice is particularly unclear, but it received expert advice that gauze is unlikely to be used to debride a wound in UK clinical practice, because its use is painful for the patient.

3.23 The Committee received expert clinical advice that the use of larvae is a valid comparator because they are now provided in bags and are regularly used in community wound management.

4 NHS considerations

System impact

4.1 The claimed system benefits in the case for adoption presented by the sponsor are that the Debrisoft pad may:

- reduce the time and resources associated with debridement, leading to a reduction in the time to healing
- achieve more effective debridement facilitating initial assessment, which may result in less frequent and fewer overall care visits
- reduce the amount of community care needed, leading to reduced overall costs, shorter waiting times for treatment and reduced referrals to hospital.

Committee considerations

4.2 The Committee considered that an improvement in clinical outcomes may result from faster treatment and healing of wounds. However, the Committee noted that evidence for the Debrisoft pad was presented as time to complete debridement rather than time to healing.

4.3 The Committee received expert advice that the Debrisoft pad would improve debridement and help further assessment and treatment of the wound. The Committee heard that it is plausible that the Debrisoft pad would debride a wound with 1 application. This may also be the same for larvae. Expert opinion was that it is likely that hydrogel and gauze would each take up to 10 applications to debride a wound. The Committee considered that using the Debrisoft pad instead of the comparators may reduce the number, length and frequency of nurse visits.

4.4 The Committee considered that the Debrisoft pad can be easily included as an option for debridement in wound management in the community. The Debrisoft pads are portable and readily available. No special arrangements are needed for

disposal of the used dressings. No evidence was presented by the sponsor to suggest that using the Debrisoft pad would reduce referrals for specialist debridement methods.

4.5 The Committee was advised that nurses and other healthcare professionals should only use the Debrisoft pad after appropriate training in how and when to use it.

5 Cost considerations

Cost evidence

Published evidence

5.1 None of the identified published studies contained cost information relating to the Debrisoft pad. The Soares (2009) study, which reported results from the VenUS II trial, was used to provide clinical effectiveness information for the comparators in the cost analysis.

Sponsor cost model

5.2 The sponsor submitted a de novo cost analysis that estimated the costs and resource consequences of using the Debrisoft pad in a community setting compared with hydrogel, gauze and larvae. Full details of all cost evidence and modelling considered by the Committee are available in the assessment report overview.

5.3 The sponsor submitted a base-case analysis for 2 community settings: a community-based clinic and home (including a residential or nursing home). The population was adults and children needing debridement of an acute or chronic wound. A single cost analysis was provided in the sponsor's submission to account for all debridement; no distinction was made between adults and children, or between acute or chronic wounds.

5.4 Clinical effectiveness information for each product was used to inform the 'number of applications to complete debridement' parameter in the cost analysis. Data from the VenUS II trial (Soares et al. 2009) were used to represent the effectiveness of larvae and hydrogel. The effectiveness of gauze was based on clinical opinion obtained by the sponsor. The effectiveness estimate for the Debrisoft pad was obtained from the Bahr et al. (2011) study. The design of this study limited the number of applications of the Debrisoft pad to 3. Results from

this study showed that 77% of wounds were completely debrided after 3 applications. In the cost analysis the remaining 23% of patients were assumed to switch to hydrogel after the 3 Debrisoft pad applications.

5.5 The sponsor's base case included several key assumptions:

- the time horizon of the analysis was the time to complete debridement of the wound
- all treatments were provided by a district nurse and were based on a wound size of 10 cm × 10 cm
- each nurse visit took 15 minutes
- the number of nurse visits per application depended on the product and its availability
- 1 wound was treated per patient.

The following parameters were based on clinical opinion:

- The Debrisoft pad and hydrogel were pre-ordered for use in a home setting but were available immediately in a clinic setting. Larvae needed pre-ordering in both settings.
- Following treatment with hydrogel, gauze and larvae, an additional nurse appointment was needed to remove them.

5.6 The External Assessment Centre corrected an error in the implementation of the sponsor's model in which 23% of Debrisoft patients switched to hydrogel (see section 5.4) but the Debrisoft costs for these patients were omitted in the original modelling. Results from the corrected model showed that:

- For the clinic setting, the total cost of complete debridement per patient was £97 for the Debrisoft pad, £165 for hydrogel, £180 for gauze, and £306 for larvae, a cost saving per patient of £68, £83, and £209 respectively.
- For the home setting, the total cost of complete debridement per patient was £189 for Debrisoft, £308 for hydrogel, £330 for gauze and £351 for larvae, a cost saving per patient of £119, £141, and £162 respectively.

5.7 The sponsor explored the uncertainty around the model parameters and the effect this had on the incremental cost of the Debrisoft pad using deterministic sensitivity analysis. The results of the corrected sensitivity analyses showed that the Debrisoft pad remained cost saving for clinic and home visits in all scenarios tested. The key drivers of the cost savings associated with the Debrisoft pad were the fewer nurse visits needed compared with hydrogel and gauze and the cheaper product costs compared with larvae.

External Assessment Centre cost model

5.8 The External Assessment Centre did not consider that all of the assumptions in the sponsor's cost model were appropriate and presented a revised cost model. Key changes were:

- the use of bagged, rather than loose larvae
- changing the cost of a district nurse to a more accurate hourly rate
- increasing the length of a district nurse visit to 22 minutes in the clinic setting and to 40 minutes in the home setting
- the cost of wound dressings was removed from visits when the debridement products had to be ordered
- using the cheapest option for the cost of hydrogel, gauze and dressings.

5.9 Results from the External Assessment Centre's revised analysis showed increased incremental cost savings for the Debrisoft pad compared with the sponsor's model. In a community clinic setting, cost savings per patient for the Debrisoft pad of £99, £152 and £375 compared with hydrogel, gauze and larvae respectively, were obtained. In a home setting, cost savings per patient for the Debrisoft pad of £211, £288 and £280 compared with hydrogel, gauze and larvae respectively, were obtained. The External Assessment Centre re-ran the sponsor's sensitivity analyses using the revised cost model and the Debrisoft pad remained cost saving in almost all scenarios. The External Assessment Centre noted that the increased cost savings were mainly a result of the longer length of nurse visits and the higher cost of bagged larvae.

5.10 The External Assessment Centre also conducted a threshold analysis to identify the number of Debrisoft pad applications needed to make it more expensive than hydrogel in 2 different scenarios:

- switching to hydrogel after a given number of Debrisoft pad applications (applying the stopping rule)
- applying the Debrisoft pad until the wound was completely debrided.

In the first scenario, the Debrisoft pad was no longer cost saving in both the home and clinic settings if the wound was not completely debrided after 7 applications and the patient had to be switched to hydrogel. In the second scenario, when the Debrisoft pad alone was used, it was no longer cost saving in the clinic setting if more than 9 applications were needed per patient and in the home setting if more than 10 applications were needed per patient.

Additional External Assessment Centre analysis

5.11 An additional base-case analysis was calculated by the External Assessment Centre based on assumptions that more closely reflect current practice in NHS community settings according to expert advice to the Committee:

- For every larvae application, 5 additional nurse visits were included to allow daily visits to assess and redress the wound.
- For home visits, the Debrisoft pad and hydrogel would be carried by the nurse and so would be available at the first visit if needed.

5.12 Results from the additional cost modelling indicated that the costs of complete debridement using the Debrisoft pad were estimated to be even more cost saving per patient compared with the use of hydrogel, gauze and bagged larvae in both community clinic and home settings. When used by a nurse in a community clinic, there were cost savings per patient of £99 for the Debrisoft pad compared with hydrogel, £152 compared with gauze and £484 compared with bagged larvae. When used by a nurse in the home, there were cost savings per patient of £222 for the Debrisoft pad compared with hydrogel, £347 compared with gauze and

£469 compared with bagged larvae.

Committee considerations

5.13 The Committee identified uncertainties in a number of the parameters in the cost analyses presented by the sponsor. The clinical effectiveness data for the products were obtained from 2 clinical trials with different methodologies and in particular the data available for the Debrisoft pad were limited. Many of the key parameters in the model were based on clinical opinion and the Committee was aware of the large variation in practice in wound care. The Committee recognised that the sponsor had tried to address the uncertainties by conducting deterministic sensitivity analyses to explore the robustness of the cost saving.

5.14 The Committee considered the additional analyses carried out by the External Assessment Centre. The Committee heard advice from clinical experts about the scenarios most likely to reflect routine clinical practice in woundcare management in the community. It agreed that the additional cost analysis (see section 5.12) was the most plausible. This model demonstrated cost savings per patient, when complete debridement was achieved, ranging from £99 to £484, depending on the comparator, in a community clinic and from £222 to £469, in the home setting. The Committee noted that although this indicates considerable cost saving for the use of the Debrisoft pad, there are also considerable uncertainties in the model because of the limited data available and the variation in clinical practice. Results from the sensitivity analyses indicated that the cost savings were robust when key parameters were varied. The Committee was also informed by the External Assessment Centre that it had re-run the cost analyses at the increased cost for the Debrisoft pad and that the results did not change substantially.

5.15 The Committee discussed the 'stopping rule' used in the model, which assumes the Debrisoft pad is used for a maximum of 3 applications and then patients are switched to hydrogel. The Committee understood this assumption was based on the limited data available from Bahr et al. (2011) and does not reflect routine clinical practice. It noted that no other switching sequences were considered in the model. Expert advice to the Committee was that for most appropriate wounds the Debrisoft pad would complete debridement in 1 or 2 applications. The

Committee noted the results of the threshold analysis conducted by the External Assessment Centre which showed that the Debrisoft pad was no longer cost saving if a wound needed more than 9 applications in the clinic setting or more than 10 applications in a home setting. Based on the clinical evidence and on expert advice, it considered these scenarios to be very unlikely.

5.16 The Committee considered that it was important to note that the cost savings demonstrated in the model do not take into account the type of treated wound. The Committee understood that there is a large variation in wound types, some of which are more suited to different debridement techniques. Expert advice to the Committee was that the Debrisoft pad was not suitable for wounds with black necrotic tissue or hard eschar. The Committee agreed that selection of an appropriate wound was important if the cost savings demonstrated in the model were to be realised.

5.17 The Committee would like to have seen a cost analysis based on time to wound healing, which could have analysed situations that routinely occur in practice when chronic wounds recur and need debriding again. However, it recognised that data were not available to inform such an analysis.

Revisions to cost model for 2019 guidance review

5.18 For the guidance review, the External Assessment Centre revised the cost model parameters to reflect 2018 values (original guidance values given in brackets). Nurse costs were inflated using the 2015/16 pay and price series. The main parameter changes were the unit costs of Debrisoft at £6.55 (£6.19, 10 cm × 10 cm), Hydrogel at £1.41 (£1.02), gauze at £0.42 (£0.39) and bagged larvae at £319 (£295). In addition, analysis was done with the larger Debrisoft pad at £16.38 (13 cm × 20 cm) and Debrisoft Lolly at £5.88. Use of the Debrisoft pad remains cost saving compared with saline and gauze (£292), hydrogel (£213) and larvae (£277) for a 10 cm × 10 cm wound area in the home setting. Larger Debrisoft pads (13 cm × 20 cm) and the Debrisoft Lolly are also cost saving in the home setting compared with saline and gauze, hydrogel and larvae. In the clinic setting, use of Debrisoft is cost saving for all 3 Debrisoft pads when compared with saline and gauze (£154 for 10 cm × 10 cm), hydrogel (£99 for 10 cm × 10 cm) and larvae (£373 for 10 cm × 10 cm). Full details are in the External Assessment

Centre cost model update report. **[2019]**

6 Conclusions

6.1 The Committee concluded that there is sufficient evidence to support the use of the Debrisoft pad in the debridement of wounds in a community setting. The Committee noted that the available evidence is mainly in adults with chronic wounds and accepted that there is little evidence specific to children or the debridement of acute wounds. The Committee also noted, from the limited available evidence, that the Debrisoft pad is particularly suited to the debridement of sloughy wounds with exudate and hyperkeratotic skin. There was some evidence that suggested that the Debrisoft pad is less successful in debriding wounds with black necrotic tissue and hard eschar. It concluded that the use of the Debrisoft pad in community clinic or home settings could lead to quicker debridement, fewer nurse visits and possibly less discomfort for the patient compared with other debridement methods.

6.2 The Committee considered that, although there is uncertainty in the cost model, the use of the Debrisoft pad could generate cost savings compared with hydrogel, gauze and larvae when used for debridement of appropriate wounds in both community clinic and home settings. The Committee concluded that overall, the case for adoption of the Debrisoft pad in the debridement of appropriate acute or chronic wounds in adults and children in a community setting was found to be supported by the evidence.

Peter Groves
Vice Chair, Medical Technologies Advisory Committee
March 2014

7 Committee members and NICE lead team

Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair)
Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair)
Consultant Cardiologist, Cardiff and Vale NHS Trust

Professor Dilly Anumba
Chair of Obstetrics and Gynaecology/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett
Lay member

Dr Keith Blanshard
Consultant Interventional Radiologist, University Hospitals of Leicester NHS Trust

Professor Nigel Brunskill

Prof of Renal Medicine, University of Leicester

Mr Matthew Campbell-Hill
Lay member

Mr Andrew Chukwuemeka
Consultant Cardiothoracic Surgeon, Imperial College Healthcare NHS Trust

Professor Daniel Clark
Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines
Consultant Vascular Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Cynthia Iglesias
Health Economist, University of York

Professor Mohammad Ilyas
Professor of Pathology, University of Nottingham

Dr Greg Irving
General Practitioner, University of Liverpool

Dr Eva Kaltenthaler
Reader in Health Technology Assessment, ScHARR, University of Sheffield

Dr Paul Knox
Reader in Vision Science, University of Liverpool

Mrs Jacqui Nettleton
Programme Director, Commissioning, Western Sussex Hospitals NHS Trust

Mrs Karen Partington
Chief Executive, Lancashire Teaching Hospitals NHS Foundation Trust

Professor Brian J Pollard
Professor of Anaesthesia, University of Manchester. Consultant Anaesthetist, Central Manchester University Hospitals

Mr Brian Selman
Managing Director, Selman and Co

Professor Wendy Tindale
Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo
Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Mr John Wilkinson
Director of Devices, Medicines and Healthcare Products Regulatory Agency

Dr Janelle Yorke
Lecturer and Researcher in Nursing, University of Manchester

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Jo Burnett
Technical Analyst

Bernice Dillon
Technical Adviser

Sue Johnson and Professor Peter Vowden
Lead Expert Advisers

Professor Peter Gaines
Non-Expert MTAC Member

Catherine Meads
External Assessment Centre Representative

Louise Longworth
External Assessment Centre Representative

Eleonora Lovato
External Assessment Centre Representative

8 Sources of evidence considered by the Committee

The External Assessment Centre report for this assessment was prepared by Birmingham and Brunel Consortium:

- Meads C, Lovato E, Longworth L. Debrisoft monofilament debridement pad for the debridement of acute and chronic wounds. September, 2013

Submissions from the following sponsor:

- Activa Healthcare Ltd.

The following individuals gave their expert personal view on the Debrisoft monofilament debridement pad by providing their expert comments on the draft scope and assessment report.

- Mr Steven John Boom, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Dr Louis Fligelstone, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Ms Sian Fumarola, ratified by the Tissue Viability Society – clinical expert
- Ms Sylvie Hampton, ratified by the Royal College of Nursing – clinical expert
- Mr Jonathan Hossain, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Ms Sue Johnson, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Mr Paul Tisi, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Ms Kathryn Vowden, ratified by the European Wound Management Association – clinical expert

- Professor Peter Vowden, ratified by the Vascular Society of Great Britain and Ireland – clinical expert

The following individuals gave their expert personal view on the Debrisoft monofilament debridement pad in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Ms Cathie Bree–Aslan, ratified by the Tissue Viability Society – clinical expert
- Mr Steven John Boom, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Dr Louis Fligelstone, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Ms Sian Fumarola, ratified by the Tissue Viability Society – clinical expert
- Ms Sylvie Hampton, ratified by the Royal College of Nursing – clinical expert
- Mr Jonathan Hossain, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Ms Sue Johnson, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Dr Douglas Orr, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Mr Duncan S W Stang, ratified by the Society of Chiropodists and Podiatrists – clinical expert
- Mr Paul Tisi, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- Ms Kathryn Vowden, ratified by the European Wound Management Association – clinical expert
- Professor Peter Vowden, ratified by the Vascular Society of Great Britain and Ireland – clinical expert
- John Reid, nominated by the Limbless Society – patient expert

Update information

March 2019: Guidance updated to include a review of the cost model using more recent values. New evidence and updated costs identified during the guidance review are denoted as **[2019]**. See the review decision for further details.

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