NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG17: The Debrisoft monofilament debridement pad for use in acute or chronic wounds

This guidance was issued in March 2014.

The review date for this guidance is October 2018.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. 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.

1. Review decision

Amend the guidance and do not consult on the review proposal.

2. Original objective of guidance

To assess the case for adoption of Debrisoft monofilament debridement pad for use in acute or chronic wounds.

3. Current guidance

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 Pressure ulcers (NICE clinical guideline 29) and Diabetic foot problems (NICE clinical guideline 119).

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, £152 and £484 respectively in a community clinic and £222, £347 and £469 respectively in the home.

4. Rationale

No new evidence has been identified which is likely to change the existing recommendations but minor changes in the product and the cost consequences should be reflected in factual amendments to the guidance.

5. New evidence

The search strategy from the original assessment report was re-run. References from 8 August 2013 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 the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The Debrisoft (L&R Medical UK Ltd) pad has been modified to include a pocket at the back to facilitate handling. In addition, 2 new versions of the technology have been introduced: the Debrisoft Lolly has a handle attached to the pad to facilitate debridement of cavity wounds and a larger size (13 x 20 cm compared with 10 x10cm original size) pad, also with a pocket at the back. The monofilament material and mode of action are unchanged since the medical technologies guidance published. The original and the larger size versions have CE marks as class I medical devices. The Debrisoft Lolly has a CE mark as a Class II medical device.

The cost of the original Debrisoft Pad (10 x 10 cm) has increased slightly from £6.27 in August 2013 to £6.55 in October 2018. The Debrisoft Lolly costs £5.88 and the larger (13x20 cm) Debrisoft Pad is £16.38.

The company has changed its name to L&R Medical UK Ltd.

5.2 Clinical practice

The NICE pathways for pressure ulcers and foot care for people with diabetes refer to the Debrisoft medical technologies guidance.

The guideline on Pressure ulcers: the management of pressure ulcers in primary and secondary care (CG29) has been updated and replaced by Pressure ulcers: prevention and management (CG179). This guideline recommends debridement as a therapy for pressure ulcer management and cites the Debrisoft medical technologies guidance (MTG17).

The guideline on Diabetic foot problems: Inpatient management of diabetic foot problems (CG119) has been updated and replaced by Diabetic foot problems: prevention and management (NG19). This guideline recommends debridement as one of the options for the standard care of diabetic foot ulcers.

5.3 NICE facilitated research

There were no research recommendations in this guidance.

5.4 New studies

The updated literature searches were carried out in 12 October 2018 and identified 7 relevant studies that are summarised here. In addition there are 6 case reports that describe results from the use of Debrisoft. These are summarised in appendix 2.

Randomised controlled trial

Zacharevskij et al (2017a) is a full paper describing a randomised controlled trial on 82 people with deep thermal burns of the forearm and hand. It appears to be the same patient group described in Zacharevskij et al (2017b), a full paper describing a randomised, controlled trial on 87 people undergoing therapy for burns of the hand. There were four treatment arms: Debrisoft followed by silver sulfadiazine ointment once daily for four to five days; hydrocolloid dressing; proteolytic enzyme gel; or control comprising only an ointment. Wounds were assessed 3, 7, 14 and 21 days post burn. The Debrisoft group exhibited a reduction in scarring using the Vancouver Scar Scale (statistics not presented). The discussion of Zacharevskij et al (2017b) suggests that the use of Debrisoft improved the ability to examine the wound surface, remove debris quickly, and promote the epithelization process. Another comment was that Debrisoft should be used with care, since exerting heavy pressure lead to massive capillary bleeding. Zacharevskij et al (2017a) described that the Debrisoft group (n=20)

healed in 19.3 days ± 2.5 compared with the control (n=21, 19.8 days ± 2.9, p<0.05). The study was conducted in Lithuania.

Cohort study

Iblasi (2018) is a full paper describing a retrospective cohort study (n=32) on people with sacral or heal pressure ulcers (mean age 61 years). People with diabetes were excluded from the study. The active intervention was use of the Debrisoft pad compared with sterile gauze. Mean pressure ulcer scale of healing (PUSH3) scores were 3.88 ± 1.25 SD for Debrisoft and 13.69 ± 1.70 SD for gauze (p<0.05). The study was conducted in Saudi Arabia.

Observational studies

Dissemond et al (2018) is a full paper describing a multicentre international user test of the Debrisoft Lolly involving 23 clinicians from 19 centres in Germany and 4 centres in the UK. Of the 155 wounds, 64 were leg ulcers, 25 were diabetic foot ulcers, 32 were pressure ulcers, 7 were post- or peri- surgical wounds and 27 described were as “other.” 41% (n=63) people had deep wounds and 20% (n=31) had cavity wounds. The Debrisoft Lolly was described as easier to use, or as easier to use, compared with the local standard of care in all cases. In 90% of procedures, the use of Debrisoft was equal or shorter in duration than local standard care. Debridement efficacy was described as “satisfactory” or “better than” local standard care by 95% of clinicians. Patient-reported pain was less (80% of procedures) or equal (20%) when compared with standard care. No adverse events were reported.

Porter (2015) is a review with additional original observational data considering the classification of pressure ulcers before and after debridement with Debrisoft. Initial results are also reported in a conference abstract by Swan & Orig (2013). For a case series of 13 people with pressure ulcers debridement with Debrisoft revealed a more superficial pressure ulcer in 8 people (61.5%). Observational data (no statistics) were presented that Debrisoft can be used to visualise the magnitude of pressure ulcers, resulting in more accurate classification.

Roes et al (2018) is a full paper giving equivalence data on the Debrisoft pads obtained from multi centre acceptance trials in Germany: 31 clinicians compared the Debrisoft pad without the hand pocket against the new design with the hand pocket (both 10 x 10cm); 34 healthcare professionals compared the Debrisoft pad (10 x 10cm) with the hand pocket against the larger pad (13 x 20cm) with the hand pocket. No clinical outcomes were assessed; this was a study into ergonomics/human factors. The results indicated that the new versions met the design criteria.

Schultz et al (2018) reported two trials of Debrisoft Pad in a full paper: the porcine model demonstrating debridement of a biofilm is out of scope as an in vitro model; 10 people were part of a clinical case series comprising wounds described as diabetic foot ulcer (n=1), trauma (n=1), venous (n=2), pressure

(n=3), surgical (n=3). All wounds demonstrated a reduction in exudate. All wound surface areas reduced in size (no statistics presented).

5.5 Cost update

The External Assessment Centre (EAC) updated the parameters in the cost model to reflect current costs and resources (O'Connell S, 2018). The cost of the Debrisoft 10cm x 10cm pad has increased from £6.19 to £6.55 and the costs of all comparator technologies have also increased marginally since the publication of the guidance. Nurse costs were also increased in the model to reflect current salary costs.

Basecase results from the updated model (see table 1) show that Debrisoft remains cost saving against all comparators in both the home and community clinic setting. The EAC also reran the model with the newer Debrisoft versions. For the larger Debrisoft pad (13x20cm) the comparator costs were amended and it was assumed more hydrogel would be used. The results show both versions are likely to be cost savings however the EAC noted caution about the accuracy of these results.

The updated savings for the Debrisoft 10x10cm pad will be included in the amended guidance, as will the cost savings for the Debrisoft 13x20cm pad and the Debrisoft Lolly.

The EAC reported:

> *"Debrisoft remains cost saving compared with saline & gauze (£292), hydrogel (£213) and larvae (£277) for 10cm x 10cm wound area in the home setting. Larger Debrisoft pads (13cmx20cm) are cost saving in the home setting compared with saline & gauze (£263), hydrogel (£185) and larvae (£311) and the smaller Debrisoft lolly (2cmx5cm) is also cost saving compared with all three comparators in the home setting: saline & gauze (£294), hydrogel (£215) and larvae (£401)."*
>
> *"In the clinic setting, use of Debrisoft is cost saving for all three Debrisoft pads when compared with saline & gauze (£154; £125 and £126 for 10cmx10cm, 13cmx20cm and 2cmx5cm respectively), hydrogel (£99; £79 and £101 for 10cmx10cm, 13cmx20cm and 2cmx5cm respectively) and larvae (£373, £343 and £345 for 10cmx10cm, 13cmx20cm and 2cmx5cm respectively)."*

Table 1: Estimated cost savings per patient for complete debridement with Debrisoft (10cmx10cm) pad compared with other technologies (from EAC cost update report).

	Saline & Gauze		**Hydrogel**		**Larvae**	
	Home	**Clinic**	**Home**	**Clinic**	**Home**	**Clinic**
Current guidance basecase (2013)	£288	£152	£211	£99	£280	£375
Updated cost model with 2018 cost	£292	£154	£213	£99	£277	£373

Table 2: Estimated cost savings per patient for complete debridement with Debrisoft new versions compared with other technologies (from EAC cost update report).

	Saline & Gauze		**Hydrogel**		**Larvae**	
	Home	**Clinic**	**Home**	**Clinic**	**Home**	**Clinic**
Debrisoft 13cm x 20 cm 25g Hydrogel* (£3.08)	£259	£121	£197	£83	£308	£340
Debrisoft lolly	£294	£156	£215	£101	£401	£375

*includes hydrogel 25g for larger wound instead of 15g used in basecase

6. Summary of new information and implications for review

The clinical evidence published since the guidance was released in 2014 supports the current recommendations. Some of this evidence includes use of the new versions of the technology, the Debrisoft lolly and the larger size pad. Both the 10x10cm and 13x20cm Debrisoft pads now incorporate a hand pocket to facilitate handing.

Three experts provided advice for this guidance review. One expert reported that the technology is in use and that people are referred for Debrisoft therapy with acute and chronic, sloughy and hyperkeratotic wounds. Two other experts did not indicate any issues with the use of Debrisoft.

The revisions to the cost model indicate that Debrisoft remains cost-saving compared with other debridement methods in both a community clinic and home setting. However as shown in EAC report table 5 the cost –saving estimates per

patient have changed. Cost modelling results also show that the Debrisoft Lolly and larger sizes are also cost saving.

This review proposal is to amend the guidance to refer to the new versions of the technology, the updated clinical guidelines and the revised estimates for the cost saving. The proposed amendments to the guidance are described in Appendix 3. No consultation on these amendments is proposed but the company will be offered the opportunity for a factual accuracy check on the revision decision paper.

7. Implications for other guidance producing programmes [delete if none]

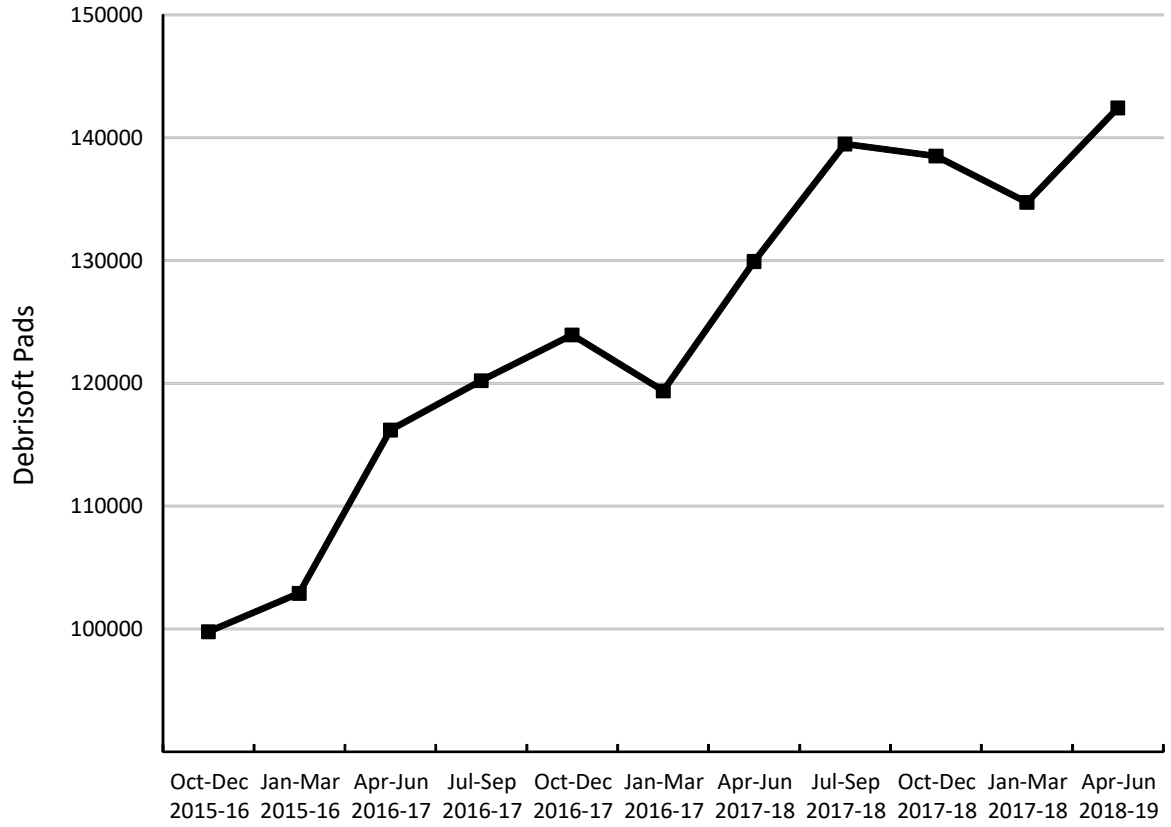
The Centre for Guidelines will consider this guidance in surveillance relevant to NG19.

8. Implementation

Information on the use of this technology within the NHS is collected in the Innovation Scorecard. Results show an increase in the adoption of Debrisoft since the guidance was published in March 2014. Debrisoft is 1 of the few technologies recommended in medical technologies guidance for which

uptake data are available because the product is available on FP10 prescription.

Figure 1 Debrisoft Pad Sales (NHS Supply Chain from NHS Innovation Scorecard)



9. Equality issues

No equality issues were identified in MTG17. No new issues have been identified.

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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

Case reports

Albas et al (2013) was a full paper describing a case study of a critically-ill person with necrotising fasciitis which developed after surgery. The person was successfully treated with further surgery, negative pressure wound therapy, and 10 days of debridement with Debrisoft at every dressing change. After 12 weeks the person had recovered sufficiently to receive only community care. This full paper appears to be the same case (title, authors, and 63 years age of person are the same) reported in a poster in the original assessment report MTG17 (Albas et al 2012). There was no comparator. The study was performed in the Netherlands. The study was supported by a grant from L&R.

Bafaraj et al (2014) was a full paper describing a case report of a person with epidermolysis bullosa, exhibiting painful leg ulcers. The leg ulcers were debrided with Debrisoft and treated with hydrogel, glucocorticoid ointment, negative pressure therapy, and skin grafts. Almost complete healing was reported at 8 months. There was no comparator. The study was conducted in Germany.

Chadwick and Findlow (2015) was a full paper describing 4 case reports demonstrating the use of Debrisoft. One patient showed wound healing over 5 weeks with Debrisoft used every 3 days. Another patient exhibited complete wound healing in 8 weeks. The paper cited MTG17 and included an algorithm for the use of Debrisoft. The study was supported by the company.

Lorenzelli et al (2018) is a review of case reports describing the use of Debrisoft for the new clinical indication of dermatological conditions such as eczema and psoriasis. Several of the studies are cited as “unpublished data on file.” All reports are positive. There is no standard clinical outcome. There is a footnote stating “this article is a promotional item commissioned by L&R UK Ltd.”

Menzies et al (2016) is a conference abstract describing a case report where Debrisoft was used as part of therapy, along with negative pressure, to treat radiation necrosis after radiotherapy. The wound only healed after therapy with larvae.

Pidcock (2013) is a full paper describing a case report where Debrisoft was used successfully to treat hyperkeratosis, a symptom of lymphovenous oedema.

References

Alblas J, Klicks R.J., and Andrlessen A. (2013) A special case: treatment of a patient with necrotising fasciitis. *British Journal of Nursing (Mark Allen Publishing)* 22 (15): S22-S26.

Bafaraj MG, Cesko E., Weindorf M. et al. (2014) Chronic leg ulcers as a rare cause for the first diagnosis of epidermolysis bullosa dystrophica. *International Wound Journal* 11 (3): 274-277.

Chadwick P, Findlow A. (2015) Understanding the role of a monofilament fibre debridement pad in the management of diabetic foot ulcers*. Diabetic Foot Journal* 18 (4): 212-216.

Dissemond J, Eberlein T., Bultemann A. et al. (2018) A purpose-designed monofilament-fibre pad for debridement of hard-to-reach wounds: experience in clinical practice. *Journal of Wound Care* 27(7): 421-425.

Gwilliam A, Greenwood B. (2018) Implementing a Mechanical Debridement Protocol Process Improvement Plan. Poster presented at SAWC Spring, 25 April 2018.

Iblasi AKS. (2018) Comparing the clinical performance of two selected mechanical wound debridement products in sloughy pressure ulcers. *Wounds Middle East Journal* 5 (1): 11-16.

Lorenzelli D, Barea A., and Morris C. (2018) A review of Debrisoft in the management of a variety of dermatological conditions. *Dermatological Nursing* 17 (2): 33-38.

Menzies S, Healy C, McMenamin M, et al. (2016) A chronic wound in the setting of sclerodermoid graft-versus-host disease and radiation. *British Journal of Dermatology* 175 (Supplement 1): 151-152. Conference abstract for poster.

O'Connell S, Withers K, Carolan-Rees G (2018) Review report of MTG17: the Debrisoft monofilament debridement pad for use in acute or chronic wounds. Cost update: December 2018. Report to NICE v1.0.

Pidcock L,Jones H. (2013) Use of a monofilament fibre debridement pad to treat chronic oedema-related hyperkeratosis. *Wounds UK* 9 (3): 85-88.

Porter M. (2015) Does debridement have a role in the accurate assessment of patients with pressure ulcers? *Wounds UK*: September Supplement p10-13. Review.

Roes C, Eberlein T., Schmitz M. et al. (2018) Improving the monofilament-fibre pad to debride wounds. *Wounds UK* 14 (4): 100-105.

Schultz GS, Woo K., Weir D. et al. (2018) Effectiveness of a monofilament wound debridement pad at removing biofilm and slough: ex vivo and clinical performance. *Journal of Wound Care* 27 (2): 80-90.

Swan J, Orig R. (2013) Debridement using a monofilament fibre pad to aid in the accurate categorisation of pressure ulcers. 16th Annual European Pressure Ulcer Advisory Panel Meeting: Vienna: 28–30 August 2013. Poster 24.

Zacharevskij E, Baranauskas G., Varkalys K. et al. (2017a) Debridement method optimisation for treatment of deep dermal burns of the forearm and hand. *EWMA Journal* 17 (1): 7-13.

Zacharevskij E, Baranauskas G., Varkalys K. et al. (2017b) Comparison of non-surgical methods for the treatment of deep partial thickness skin burns of the hand. *Burns* 44:445-452.

Registered and unpublished trials

Trial name and registration number	Details
None.	All registered trials have been published.

Appendix 3 – changes to guidance

Table 1: proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
Page 1, 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 Pressure ulcers (NICE clinical guideline 29) and Diabetic foot problems (NICE clinical guideline 119).	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 Pressure ulcers (NICE clinical guideline 179) and Diabetic foot problems (NICE guideline NG 19). [2019]
Page 1, 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, £152 and £484 respectively in a community clinic and £222, £347 and £469 respectively in the home.	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]
2.1	The Debrisoft monofilament debridement pad (Activa Healthcare) is a sterile, single-use pad for nurses and other healthcare professionals for use on adults and children to remove devitalised tissue, debris, and hyperkeratotic skin around acute or chronic wounds. It is 10×10 cm and is made of monofilament polyester fibres with a reverse side of polyacrylate. The	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

	monofilament fibres are cut with angled tips designed to penetrate irregularly shaped areas and remove devitalised skin and wound debris.	with angled tips designed to penetrate irregularly shaped areas and remove devitalised skin and wound debris. There are two sizes of pad (10×10 cm and 13x20cm, both with a hand pocket to facilitate handling) and a version with a handle (Debrisoft Lolly). [2019]
2.6	Pressure ulcers (NICE clinical guideline 29) 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 pressure ulcer management pathway.	Pressure ulcers (NICE clinical guideline 179) 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 pressure ulcer management pathway.[2019]
2.7	Diabetic foot problems (NICE clinical guideline 119) 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.	Diabetic foot problems (NICE guideline 19) 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]
5.18		For the guidance review, the external assessment centre revised the cost model to reflect 2018 costs (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, 10cm x 10cm), Hydrogel at £1.41 (£1.02), gauze at £0.42

		(£0.39) and bagged larvae at £319 (£295). In addition, the larger Debrisoft pad at £16.38 (13cm x 20cm) and Debrisoft Lolly at £5.88 were included. Debrisoft remains cost saving compared with saline & gauze (£292), hydrogel (£213) and larvae (£277) for 10cm x 10cm wound area in the home setting. Larger Debrisoft pads (13cmx20cm) and the Debrisoft Lolly are cost saving in the home setting compared with saline & gauze), hydrogel and larvae. In the clinic setting, use of Debrisoft is cost saving for all three Debrisoft pads when compared with saline & gauze (£154 for 10cmx10cm), hydrogel (£99 for 10cmx10cm) and larvae (£373 10cmx10cm). Full details are in the EAC cost model update report. [2019]