NICE National Institute for Health and Care Excellence

NICE guidance

3C Patch for treating diabetic foot ulcers

HealthTech guidance
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www.nice.org.uk/guidance/htg615

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

This guidance replaces MTG66 and MIB230.

1 Recommendations

1.1 3C Patch is not recommended as a cost-saving option for diabetic foot ulcers.

Why the committee made these recommendations

Diabetic foot ulcers are treated by reducing pressure on the ulcer, removing damaged tissue, controlling poor blood flow and using dressings, including UrgoStart or other advanced dressings. The 3C Patch system uses a person's own blood to create a biological patch that promotes wound healing. It is intended to be used for diabetic foot ulcers that have not healed after 4 weeks of treatment.

The clinical evidence on ulcers that are not healing shows that using 3C Patch led to more ulcers healing at 20 weeks and faster ulcer healing. However, there were uncertainties around whether the evidence would generalise to current NHS practice because of how and when the treatment would be used. Cost analysis also showed that the clinical benefits seen in the trial are unlikely to lead to cost savings in practice. Therefore, 3C Patch cannot be recommended.

2 The technology

Technology

2.1 3C Patch is a single-use medical device that is used as part of wound care for foot ulcers in people with diabetes. 3C Patch is used in combination with the 3CP centrifuge. Together the device and the centrifuge are referred to as the 3C Patch system.

2.2 The system is used to make an individual, biological patch from a person's own blood. The patch is a disc-shaped layered matrix of fibrin, leukocytes and platelets and acts as a concentrated source of cells, growth factors and signalling molecules, which are thought to promote wound healing.

2.3 To make the patch, blood is drawn directly into the 3C Patch device, and then spun for about 20 minutes in the 3CP centrifuge. The centrifuge has optical sensors and uses an automatic prespecified programme that performs all the steps needed to create the patch. The patch is applied directly to the ulcer and kept in place with a non-adhesive primary dressing. A separate secondary dressing can also be used to manage exudate.

Care pathway

2.4 This evaluation focuses on the use of 3C Patch for the treatment of diabetic foot ulcers (DFUs) that are not healing despite standard care. Current care for DFUs (as outlined in NICE's guideline on diabetic foot problems: prevention and management) includes offloading, debridement, control of ischaemia, and use of dressings. It recommends that clinical assessment and patient preference are taken into account when choosing dressings, but healthcare professionals should choose the lowest cost dressing that is likely to achieve the desired results. This could include use of advanced dressings such as UrgoStart (see NICE's medical technologies guidance on UrgoStart for treating diabetic foot ulcers and leg ulcers). NICE's diabetic foot guideline recommends that other treatments like

dermal or skin substitutes should only be considered as an adjunct to standard care when healing has not progressed. The guideline also recommends that other treatments, including autologous platelet-rich plasma gel, should only be used as part of a clinical trial.

2.5 3C Patch is intended to be applied and replaced every 7 days. The company recommends that 3C Patch should be considered when 4 weeks of treatment with standard care has not reduced the ulcer area by at least 50%. The company suggests 3C Patch treatment should be used for 4 to 6 weeks initially, and up to 20 weeks in total, depending on response to treatment as measured by reduction in ulcer area.

Innovative aspects

2.6 3C Patch is innovative because it uses the person's own blood sample, which is then centrifuged to create a solid patch, with no additional reagents needed from outside the person's body. Immune cells, platelets and growth factors captured in the patch are associated with the processes of tissue repair and the inflammatory response.

Intended use

2.7 3C Patch is indicated for the management of recalcitrant wounds. The scope of this evaluation is limited to its use for the treatment of DFUs that are not healing despite standard wound care. For this population, the intervention is usually delivered in a multidisciplinary diabetic foot clinic. Healthcare professionals involved in delivering the intervention need to be trained on preparing and applying the patch.

Costs

2.8 The 3C Patch kit costs £150 (excluding VAT) and can be used to make 1 patch. Each kit includes the 3C Patch device, needle holder, winged blood sampling set

with protector, primary cover dressing (Tricotex), alcohol swab, post-blood-sample adhesive bandage and a ruler with adhesive. The 3CP centrifuge is provided on loan by the company free of charge. Servicing and maintenance of the 3CP centrifuge is also free of charge and the expected lifespan of the centrifuge is at least 7 years. A non-sterile 3CP counterbalance is also needed for balancing the centrifuge.

For more details, see the website for 3C Patch.

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

The main clinical evidence comprises 4 studies, 1 of which is a randomised controlled trial

3.1 The EAC assessed 4 studies including 332 people with diabetic foot ulcers (DFUs). One study was a randomised controlled trial (RCT; n=266) and 3 were case series, 1 of which was published as an abstract (the case series included 44, 5 and 17 people). Two further studies identified by the company were not included by the EAC because these were not relevant to the decision problem. For full details of the clinical evidence, see section 3 of the assessment report.

The RCT was well conducted but some aspects of the design do not reflect NHS practice

3.2 The Game et al. (2018) RCT was considered to provide the best available data on the use of 3C Patch in relation to the decision problem. This was because it is a UK-based RCT that included people whose ulcers had a less than 50% reduction in area after 4 weeks of standard care (described as 'hard-to-heal' ulcers by the study authors). The trial also measured clinically relevant outcomes and the EAC judged it to have a low risk of bias. However, the EAC noted some issues with the generalisability of the results to current clinical practice. Expert advice indicated that, following the publication of NICE's medical technologies guidance on UrgoStart for treating diabetic foot ulcers and leg ulcers, UrgoStart has become the standard of care. As the Game et al. study took place between 2013 and 2017, only 1 person had UrgoStart in the run-in period. Other protease modulating dressings (classified by the BNF) were used by 2% of people during the run-in.

Additionally, clinical experts had different opinions on whether 3C Patch would be continued if there was an infection and advised that the treatment will be at least temporarily halted to evaluate the infection severity. The EAC noted that 3C Patch treatment was continued while ulcers were infected in the Game et al. trial in most cases, in line with the trial protocol. The EAC concluded that although the trial was well conducted, some aspects of the study design may not reflect NHS practice.

The company's proposed stopping rule was not used in the RCT

3.3 The EAC noted the way the intervention was delivered in the trial did not align to the company's proposed treatment pathway. The company stated that 3C Patch use should be reviewed after 4 to 6 weeks and stopped if adequate progress in healing has not been seen, such as a reduction of 50% or more in ulcer area. This stopping rule was not followed in the clinical trial because everyone in the treatment group had 3C Patch until healing or up to 20 weeks. Clinical experts stated that a 50% ulcer area reduction rule to mark adequate healing progress is not routinely used in practice to judge response to treatment. The EAC considered this an important limitation of the evidence base.

3C Patch increases the proportion of people with complete epithelialisation or healing at 20 weeks in the trial population

3.4 RCT evidence (Game et al. 2018) found that 34% of ulcers (45 out of 132) in the intervention group had complete epithelialisation or healing at 20 weeks compared with 22% (29 out of 137) in the standard care group (odds ratio 1.58; 95% confidence interval [CI] 1.04 to 2.40; p=0.0235). In the case series, healing rates at 20 weeks were 52% (23 people out of 44) and 61.9% (13 ulcers out of 21; Löndahl et al. 2015 and Katzman et al. 2014, respectively).

3C Patch reduced time to healing and ulcer area at 20 weeks in the trial population

3.5 RCT evidence (Game et al. 2018) found that 3C Patch reduced time to healing compared with standard care over 20 weeks (hazard ratio 1.709; 95% CI 1.071 to 2.728; p=0.0246). In the subgroup that had healed at 20 weeks, the median time to healing was 72 days (interquartile range [IQR] 56 to 103) in the 3C Patch group compared with 84 days (IQR 64 to 98) in the standard care group (difference 12 days; p=0.0343). This study also found a statistically significant decrease in ulcer area over a 20-week period in the 3C Patch group (p=0.0168).

Evidence does not support 3C Patch reducing the risk of amputation or ulcer infection and direct clinical evidence for the other company-claimed benefits is limited

3.6 Game et al. (2018) found no significant difference in those with a new infection within 20 weeks, visits reporting infection (as a proportion of total visits) or total days of antibiotic therapy. The study also found no significant difference in new minor or major amputations affecting the index or contralateral limb. However, the study was not powered to detect differences in these parameters. The EAC further noted that although there was a reduced time to healing seen, no data on the demand for care across NHS settings (outpatient, community, primary and inpatient) were presented. Any improvement in quality of life was uncertain as these measures were only reported in an abstract for a small subgroup of people (10 people in the 3C Patch group and 8 people in the standard care group, all with ulcers extending into tendons; Löndahl et al. 2019).

Cost evidence

The company's cost model uses a Markov model comparing 3C Patch with standard care in those with hard-to-heal DFUs

3.7 A Markov model was used to estimate costs and quality-adjusted life years

associated with the use of 3C Patch plus standard care compared with standard care alone. It took into account the impact of each treatment option on the likelihood of healing, re-ulceration, major amputation, minor amputation and death over a 2-year time horizon. The population included in the model were those with hard-to-heal DFUs, which aligned with the population included in Game et al. (2018). For full details of the cost evidence, see section 4 of the assessment report.

The company's cost model uses a stopping rule for 3C Patch treatment and makes use of data from an unplanned post-hoc analysis of the trial

3.8 The company's model included a number of assumptions that reflect the company's proposed use of 3C Patch within the DFU treatment pathway. It incorporated an assumption that 3C Patch use would be stopped if an ulcer has not reduced in area by 50% or more within 5 weeks of treatment. This stopping rule was not used in the Game et al. (2018) trial, so the company did an unplanned post-hoc analysis of the trial data to generate the following clinical inputs:

- the proportion of people who would stop 3C Patch treatment at 5 weeks (57.9%)
- healing rates with 3C Patch at weeks 0 to 5, weeks 6 to 20 and week 21 onwards
- healing rates for people who would stop using 3C Patch after week 5 if a stopping rule had been applied.

The company's model structure is appropriate, but the EAC created a second model to consider a 'moderate or severe' infection state

3.9 The EAC judged the overall model structure and time horizon to be appropriate. However, it disagreed with some of the key clinical and cost parameters used in

the company's model (see sections 3.10 to 3.13). Additionally, in light of the varying clinical expert views on whether 3C Patch use should continue when an ulcer is infected (see section 3.2), the EAC created a second model (model B) that added a 'moderate or severe' infection state. In this state, people with a moderate or severe infection stop using 3C Patch until their ulcer is no longer infected. The company's model did not have a separate infection state as it followed the protocol used in the Game et al. (2018) RCT whereby 3C Patch was not stopped while an ulcer was infected. Instead, the company's model included infections as recorded in the RCT, with their associated impact on costs and healing rates.

The EAC made changes to the costs used in the company's model

3.10 The EAC made amendments to the costs in the base-case model by using resource use data, when possible, from an unpublished economic analysis of the Game et al. (2018) RCT (Farr et al., unpublished). These changes included adjusting the number and length of outpatient visits and adjusting the proportion of people having inpatient procedures. Dressing costs were also changed from BNF to supply chain. Additionally, the EAC made 3 further changes to the cost inputs:

- changed relative costs to absolute costs for additional care for dressing changes, done by district nurses, between outpatient consultations (in both arms of the model)
- removed the cost of a district nurse to avoid double counting in the EAC model (as the EAC changed the way in which district nurse costs were included in their model when compared with the company's model) for outpatient and community care costs (in both arms of the model)
- applied cost of training up front (as opposed to weekly).

These changes resulted in almost all costs in the EAC model being updated.

The EAC revised 3C Patch discontinuation rates in the model

3.11 As stated in section 3.7, the company model included a stopping rule applied in the 3C Patch arm, which was implemented at week 5. The EAC noted that in Game et al. (2018), everyone in the treatment arm continued to use 3C Patch until healing or for up to 20 weeks. It also noted that clinical experts stated that the stopping rule used in the company model was unlikely to be implemented in clinical practice. This is because 3C Patch treatment would likely continue if any significant improvement in ulcer size is seen when compared with previous treatments. Therefore, the EAC changed the discontinuation rate to 0% (meaning everyone in the treatment arm would continue 3C Patch until healing or for 20 weeks).

The EAC revised the healing rates in the model in line with published RCT data and its preferred discontinuation rates

3.12 As noted in section 3.7, the healing rates in the company's model were based on an unplanned post-hoc analysis of the Game et al. (2018) trial data. The EAC revised these parameters in their model to reflect the healing and discontinuation rates seen in the intention-to-treat population published in the RCT (Game et al.). This was because the post-hoc analysis excluded a substantial amount of the data, particularly for healing at 6 to 20 weeks in the 3C Patch arm. This increased uncertainty in the probabilities of healing used in the model. This was important because the probability of healing with 3C Patch in weeks 6 to 20 was a key driver in the company model and an absolute reduction in healing rate of around 0.6% changed the direction of the company's cost case.

The EAC's base case suggests that 3C Patch is cost incurring compared with current care

3.13 The company's base-case results showed cost savings of £191 per person over 2 years when 3C Patch is used instead of standard care. But, the EAC's base-case results found that 3C Patch is cost incurring compared with standard care. The incurred costs were £1,590 per person over 2 years when modelled without an infection state (model A) and £1,993 when modelled with an infection state

(model B).

The EAC's sensitivity analysis found the cost of index ulcers and discontinuation rate to be the biggest cost drivers

3.14 The EAC's sensitivity analysis found that the biggest cost drivers in the economic model were the probability of discontinuing 3C Patch and the cost of ulcer treatment when using 3C Patch, standard care or when 3C Patch is discontinued and replaced with standard care. The EAC did a 2-way sensitivity analysis to explore the impact of varying the probability of discontinuing 3C Patch and the probability of healing with 3C Patch in weeks 6 to 20 simultaneously. The EAC recognised that there is likely to be interaction between these variables. The results suggested that if there is no discontinuation of treatment at 5 weeks (0% discontinuation rate), and weekly healing rates after week 5 are over 4.5%, then 3C Patch would be cost saving. However, this healing rate is significantly higher than the rate used in the EAC base case (2.7%), which was aligned with the Game et al. (2018) RCT.

4 Committee discussion

Clinical-effectiveness overview

The committee recognised that there is an unmet need for new treatments for hard-to-heal diabetic foot ulcers and that 3C Patch is biologically plausible

4.1 The committee acknowledged that there is biological plausibility in the device's mechanism of action. This is because the device separates and concentrates autologous blood components associated with tissue healing, including platelets, growth factors and immune cells involved in the inflammatory response. It is feasible that the components forming the biological patch could promote ulcer healing. The committee also acknowledged that hard-to-heal diabetic foot ulcers (DFUs) can reduce quality of life. It stated that there is an unmet need for new treatments for these ulcers and recognised that not all treatments will work for all ulcers. The committee was concerned that the treatment program, with weekly appointments and blood draws, would be difficult to follow for some people. Clinical and patient experts stated that the 3C Patch treatment program would likely be adhered to if progress is seen. This is because those who are likely to be considered for 3C Patch already have ulcers that are not healing despite standard care and have become chronic. However, it was still appreciated that weekly visits to secondary care could be challenging for some people because of difficulties with transportation or regularly taking time off work. The committee acknowledged that for some people, 3C Patch might fulfil an unmet need in DFU care.

Randomised controlled trial evidence shows improvements in ulcer healing for a proportion of people

4.2 The main evidence presented was from a well-conducted randomised controlled trial (RCT) done mostly in the UK. The committee acknowledged the strengths

and limitations noted by the external assessment centre (EAC; see sections 3.1 to 3.3). Clinical experts confirmed that the trial population was broadly in keeping with the population of interest. However, they were unsure if the results of the current study would have been different if UrgoStart (see NICE's medical technologies guidance on UrgoStart for treating diabetic foot ulcers and leg ulcers) had been used by everyone in the run-in period. The committee considered the lack of data in an UrgoStart-experienced population to be an important evidence gap. The committee also noted that a sizeable group of people healed with standard care (22% in the RCT at 20 weeks), and clinical experts were not able to identify a subgroup of people who would be unable to heal with standard care but likely to heal with 3C Patch. Overall, the committee accepted that 3C Patch had some beneficial impact relative to other dressings for a proportion of people in the trial population. However, it is not possible to further identify those people most likely to benefit and it remains unclear whether the same impact would be observed if the treatment is used after UrgoStart.

Other patient benefits or issues

The use of 3C Patch should be re-evaluated while wounds have an infection

4.3 The committee recognised that there was a clinical rationale for discontinuing 3C Patch when infection was present. The company acknowledged that it may be clinically appropriate to stop 3C Patch treatment if there was a moderate or severe infection, but that treatment could continue if the infection was mild. Clinical experts agreed that clinical judgement around 3C Patch treatment continuation is needed when an ulcer becomes infected. The committee concluded that 3C Patch should not be used in those with moderate or severe infections. It also noted that this did not happen in most cases in the RCT, which added uncertainty to the clinical evidence and company cost case.

Blood sampling and blood disorders could affect appropriateness of 3C Patch treatment

4.4 Clinical experts stated that some people with diabetes may struggle to have weekly blood draws, making 3C Patch challenging and potentially distressing. The committee also questioned the suitability of the patch for people with certain blood conditions. The Game et al. (2018) RCT excluded people with platelet counts below 100×10^9/litre and other clinically significant blood disorders. The committee was concerned that there was no evidence on the impact these conditions could have on patch coagulation, efficacy and the ability to have weekly blood sampling. It also noted that for people on anticoagulation therapy, patch formation may take longer, leading to longer appointment times. Clinical experts stated that weekly blood draws did not seem to lead to anaemia and that patch coagulation could vary independently of blood disorders. The committee concluded that blood sampling and blood disorders should be considered when selecting treatment options, but this should not prevent 3C Patch usage.

NHS considerations overview

3C Patch could have an impact on service organisation, depending on how they are currently structured

4.5 There is variation in the organisation of diabetic footcare services across the NHS. Some clinical experts stated that 3C Patch use could make up a relatively small proportion of their foot clinic referrals. The use of 3C Patch would also have a limited impact on appointment times because the appointments have been structured to accommodate blood taking and centrifugation time. Some centres also have podiatrists and nurses trained in blood taking or have phlebotomists available to help with 3C Patch preparation. Although 3C Patch needs weekly appointments, some clinical experts noted that there are weekly appointments for other care options, especially for those with hard-to-heal ulcers. The committee heard from another expert that when 3C Patch is not currently being used, there may not be the resources available to introduce the service. The committee concluded that in some settings, 3C Patch use may need some reorganisation of services and potentially an increase in use of NHS resources including time,

space for equipment and staffing requirements.

Cost modelling overview

The stopping rule applied in the 3C Patch arm of the company model is not appropriate

4.6 The committee agreed with the EAC that the model structure was generally appropriate, and modelling discontinuation for infection by the inclusion of a moderate or severe infection state was justified based on clinical opinion. It also agreed with the concerns raised by the EAC around the stopping rule used in the 3C Patch arm. The committee recognised that the key concerns were that:

- The stopping rule was not used in the Game et al. (2018) RCT and there was no evidence on how this rule would work in practice.
- A lack of access to digital wound-measuring tools may make wound area changes more difficult to track.
- Clinical experts felt that any notable improvement in healing would justify continuation of the patch and that the 50% rule was difficult to follow in practice.
- The use of a strict stopping rule, when progress is being seen but the 50% threshold is not met, could have a negative effect on the physical and mental wellbeing of the patient.

  Clinical experts stated that they would review ulcer healing at 4 to 6 weeks of treatment and regularly thereafter. They would measure any improvement relative to the rate of healing before 3C Patch use and stop treatment if there was no or limited progress. The company clarified that the 5-week stopping rule was used as a proxy for discontinuation of 3C Patch at any point within the 20-week period. It also stated that healing at 5 weeks was a good predictor of healing at 20 weeks, based on analysis of patient-level data. The company suggested that further research could be done, using a Delphi Panel or a Sheffield Elicitation Framework (SHELF) methodology, to inform

what stopping rule to use in clinical practice and how long 3C Patch treatment would continue. The EAC confirmed that further clinical evidence collection would be needed alongside this to reduce uncertainty in the economic model after the implementation of the proposed stopping rule. Overall, the committee acknowledged that a stopping rule would be needed in the economic model, but that there was currently no clarity on what the most appropriate rule would be.

Economic modelling is limited by the available clinical evidence and its relevance to the proposed NHS clinical pathway

4.7 The committee recognised the uncertainty in the healing rates used in the company model as outlined by the EAC. This includes the use of unplanned post-hoc analyses when data used was based on 42% of people in the 3C Patch arm (for weeks 6 to 20). It also acknowledged that there was no clinical evidence on the healing rates for those who would stop 3C Patch treatment if a stopping rule had been used in the trial. The committee recognised that the EAC's modelling, based on healing rates in the intention-to-treat population, resulted in very different cost estimates. This highlighted the impact of the uncertainty in the healing rate parameters. It also noted that because the EAC analysis included no discontinuation of treatment at all, it was unlikely to provide a true estimate of the cost impacts of 3C Patch. The committee concluded that the lack of direct clinical trial evidence for the company's proposed treatment pathway is a major limitation of the economic analysis.

The EAC and company used different data sources in the cost modelling, which changed the direction of the cost case for 3C Patch

4.8 The committee heard that EAC changes to the data sources used in the cost modelling meant that the overall cost of 3C Patch was increased by around £800 in the EAC's model A (a model without a separate infection state). The EAC confirmed that although the Farr et al. report was unpublished, it was based on direct trial evidence rather than a more general published study on the cost of

DFUs to the NHS in England (Kerr et al. 2019). It was acknowledged that both sources of data had limitations but the EAC's approach using costs from Kerr et al. (2019) with resource use data from Farr et al. (unpublished) was preferred given that it uses direct trial evidence that is most relevant to the population. The committee was concerned that changing the source of the costs for the economic model was sufficient to make 3C Patch cost incurring. It concluded that the EAC changes to the costs further highlighted the uncertainty in the company base case for 3C Patch.

The company's base case is unstable and 3C Patch is unlikely to be cost saving

4.9 The committee acknowledged that the only way to offset the higher upfront costs of 3C Patch treatment was to reduce the resources needed later in the pathway for managing unhealed ulcers and their complications. It acknowledged that the company had presented results that indicated that such savings were possible. But the committee noted that these results were based on a model populated with uncertain clinical and cost inputs that had been questioned by the EAC. The committee also noted that varying the model inputs for treatment discontinuation, healing rates and inpatient and outpatient care costs, within ranges that reflected the uncertainty in the underlying data, led to a change in direction of the cost case for 3C Patch. Further to this, the committee noted that if 3C Patch is discontinued because of an ulcer having a moderate or severe infection, the EAC's model B (which included an additional state to capture moderate or severe infections) may be the most appropriate model structure. It acknowledged that this model led to 3C Patch being more cost incurring. The committee considered that the EAC's 2-way sensitivity analysis was helpful in demonstrating that there are few combinations of discontinuation and healing rates that can lead to 3C Patch becoming cost saving, with the combinations that were associated with cost savings being less clinically plausible. It also noted that the company model was sensitive to changes in the cost parameters and that using the EAC's costs alone (without adjusting the company's healing and discontinuation rates) also led to 3C Patch becoming cost incurring. The committee concluded that the case for adoption was not supported because the estimated cost-saving case presented by the company was not robust. Large savings in care costs would be needed to offset the cost of 3C Patch and there

was insufficient evidence presented to show that care needs would be significantly reduced after 3C Patch treatment.

Potential research

Additional research could help address uncertainties in the evidence, although the case for cost savings remains unlikely

4.10 Although the committee acknowledged that the Game et al. (2018) RCT was well conducted, it felt that additional research could help resolve some uncertainties around the cost and clinical case for 3C Patch. Specifically, research identifying the most appropriate stopping rule, and the associated clinical outcomes of implementing the rule, would help address key uncertainties within the cost case. Additional collection of resource use data on unhealed hard-to-heal ulcers could also reduce uncertainty in the cost case. Further to this, evidence could be collected on an UrgoStart-experienced population, as this would be reflective of current NHS care. Clinical experts thought a trial on this population would be feasible. The committee concluded that although further research could be done, on balance it was unlikely to result in a cost-saving case for 3C Patch based on the decision problem evaluated in this guidance.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

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

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Update information

Minor changes since publication

December 2025: Medical technologies guidance 66 has been migrated to HealthTech guidance 615. The recommendations and accompanying content remain unchanged.

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