NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

3C Patch for treating diabetic foot ulcers

How medical technology guidance supports innovation

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 The case for adopting 3C Patch for diabetic foot ulcers is not supported. Cost modelling shows that using 3C Patch is unlikely to lead to savings.

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. But, cost analysis for

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3C Patch 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 focusses 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 used 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

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dressings such as UrgoStart (see NICE's medical technology 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 used and replaced every 7 days. The company recommends that 3C Patch should be considered where 4 weeks of treatment with standard care has not reduced ulcer area by at least 50%. The company suggest 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 from outside the person's body needed. 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 delivered in a multidisciplinary diabetic foot clinic in secondary care. Healthcare professionals involved in delivering the intervention need to be trained on preparing and applying the patch.

Costs

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),

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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

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clinically relevant outcomes and the EAC judged it to have a low risk of bias. However, the EAC noted some issues with the external validity of the trial. Expert advice indicated that, following the publication of NICE guidance in 2019, UrgoStart has become the standard of care. As the Game et al. (2018) study took place between 2013 and 2017, only 1 person received UrgoStart in the run-in period, although other protease modulating dressings were used by 40% of people during the run-in. Entry into the treatment phase of the trial was determined by a decision rule (failure to respond to standard care provided in the run-in period, based on a reduction of less than 50% in ulcer area). Clinical experts stated that this rule is not routinely used in practice to judge response to treatment. It is also unlikely to be readily implementable across different settings because accurate ulcer-area measuring tools are not widely available in the NHS. Also, other factors may be used in clinical practice to assess treatment response and eligibility for 3C Patch, such as lack of ulcer offloading, infection status or poor blood supply. Clinical experts also had different opinions on whether 3C Patch would be continued if there was a moderate or severe ulcer infection. The EAC noted that 3C Patch treatment was continued while ulcers were infected in the Game et al. (2018) trial. The EAC concluded that although the trial was well conducted, some of the aspects of the study design may not be reflective of 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 there has not been a 50% reduction 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. The EAC considered this an important limitation of the evidence base.

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3C Patch increases the proportion of people with complete epithelialization 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 epithelialization 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 there was insufficient direct trial evidence to support claimed benefits around reducing demand for ulcer care and reducing follow-on treatments. Any improvement in quality of life was uncertain as these measures were only

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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 with 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 conducted an unplanned post-hoc analysis of the trial data to generate the following clinical inputs:

- 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 discontinue 3C Patch after week 5 if a stopping rule had been applied.

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The company's model structure is appropriate but does not account for 3C Patch discontinuation due to infection

3.9 The EAC judged the overall model structure and time horizon to be appropriate. However, it identified some errors in the company costing and 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 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 EAC corrected cost errors found in the company's model

3.10 The EAC corrected 3 errors in the costs used in the company model:

- changed relative costs to absolute costs for additional care for dressing changes, done by district nurses, between outpatient consultations (in both arms of model)
- removed the cost of a district nurse to avoid double counting in outpatient and community care costs (in both arms of the model)
- applied cost of training up front (as opposed to weekly).

The EAC revised 3C Patch discontinuation rates in the model

3.11 As noted 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 3C Patch use until healing or 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 accurately measuring ulcer size would need specialist equipment and 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).

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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. 2018). 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 a small reduction in healing rate (around 0.6%) changed the direction of the company's cost case.

The EAC made a number of amendments to the costs used in the base case model

3.13 The EAC made a number of amendments to the costs in the base case model including using resource use data, where possible, from an unpublished economic analysis of the Game et al. (2018) RCT (Farr et al., unpublished). The EAC changes to cost inputs, as well as the corrections made to cost errors, resulted in almost all costs in the EAC model being updated. These included changing dressing costs from BNF to supply chain, adjusting number and length of outpatient visits and adjusting the proportion of people having inpatient procedures.

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

3.14 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).

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

3.15 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 where 3C Patch is discontinued and replaced with standard care. The EAC performed 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 and also used a 0% discontinuation rate.

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 there is an unmet need for new treatments for hard-to-heal diabetic foot ulcers (DFUs) and that not all treatments will work for all ulcers. The committee were concerned that the treatment program, with weekly appointments and blood draws, would be difficult to follow for

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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 proportion and time to healing but the clinical importance of the observed benefit is uncertain

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 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 it questioned the degree to which the statistically significant changes seen in the trial (12% more ulcers healing at 20 weeks and a 12-day reduction in ulcer healing time in the 3C Patch arm compared with standard care) were clinically meaningful. The committee also understood that it was not currently possible to identify a subgroup in which 3C Patch was more clinically effective compared with the overall trial population. 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 remains unclear whether the same impact would be observed if the

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treatment is used at the appropriate position in the current NHS treatment pathway. The committee were also uncertain of the clinical importance of the difference in healing time and healing rate shown in the evidence.

Other patient benefits or issues

3C Patch treatment should be halted whilst wounds have a moderate or severe infection

4.3 The committee recognised that there was a clinical rationale for discontinuing 3C Patch where 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. The committee concluded that 3C Patch should not be used in those with moderate or severe infections. It also noted that because this did not happen in the RCT, this adds 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 participants with platelet counts below 100×10^9/l and other clinically significant blood disorders. The committee were 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.

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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 has a relatively limited impact on appointment times. This is 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 they have weekly appointments for other care options, especially for those with hard-to-heal ulcers. The committee heard from another expert that where 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 require some reorganisation of services and potentially an increase in NHS resource use in terms of time, space for equipment and staffing requirements.

Devices to accurately measure ulcer area are not available across the NHS

4.6 Clinical experts stated that digital devices for accurately measuring ulcer area are not consistently available across the NHS, with some centres using a ruler or visual inspection to assess wound healing progress. They stated that this is due to the current cost of these devices. The committee heard that access to digital ulcer-size measuring devices should increase following recommendations being made by the national wound care strategy.

Cost modelling overview

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

4.7 The committee agreed with the EAC that the model structure was generally appropriate and modelling discontinuation for infection via the

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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
- the stopping rule would not be easy to implement in practice due to a lack of accurate wound measuring tools
- 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 where progress is being seen but the 50% threshold is not met, would 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 prior to 3C Patch use and stop treatment if there was no or limited progress. The company agreed with the clinical experts but 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. Overall, the committee acknowledged that a stopping rule would be needed in the economic model, but that there was no clarity on what the most appropriate rule would be.

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

4.8 The committee recognised the uncertainty in the healing rates used in the company model as outlined by the EAC. This includes use of post-hoc analyses where data used was based on 42% of people in the 3C Patch

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arm (for weeks 6 to 20). It also acknowledged that there was no clinical evidence on the likely healing rates for those who would discontinue 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 published RCT, 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

4.9 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. 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 DFUs to the NHS in England (Kerr et al. 2019). It was acknowledged that both sources of data had limitations but felt that Farr et al. (unpublished) was a reasonable alternative source of data given that it is appropriate to use direct trial evidence where possible. The committee were 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

4.10 The committee acknowledged that the only way to off-set 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

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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 due to an ulcer having a moderate or severe infection, the EAC's model B may be 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 making adjustments to 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.

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.

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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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