NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

3C Patch for treating diabetic foot ulcers

1 Technology

1.1 Description of the technology

3C Patch (Reapplix) is a single-use medical device that makes an autologous biological patch from a patient blood sample. The patch is used as part of wound care for foot ulcers in people with diabetes.

Each 3C Patch device is sold as part of a kit that contains one each of the following:

- 3C Patch device
- 3C Patch needle holder
- winged blood sampling set (G21) with protector
- primary cover dressing (Tricotex)
- alcohol swab (for disinfection of the skin before needle insertion)
- post blood sample adhesive bandage
- ruler with adhesive

The 3C Patch device is used in combination with the 3CP centrifuge (together the device and the centrifuge are referred to as the 3C Patch system). The 3CP centrifuge is provided on loan by the company free of charge. Servicing and maintenance of the 3CP centrifuge are also free of charge and the expected lifespan of the centrifuge is at least 7 years.

To make the autologous biological patch, a small sample of the patient's peripheral blood is drawn directly into the 3C Patch device. The device is then placed in the 3CP centrifuge and spun for about 20 minutes. This process results in a disc-shaped layered matrix of fibrin, leukocytes and platelets forming without the need for any additional reagents. The patch is applied directly to the ulcer and kept in place with a non-adhesive dressing. A separate secondary dressing can also be used to manage exudate. The treatment lasts 7 days, during which time the patch dissolves. According to the instructions for use, 3C Patch is used once a week for up to 20 weeks, at the discretion of the treating healthcare practitioner. The company recommends using 3C Patches for 4 weeks to 6 weeks initially and then to continue only in those patients who show improvement.

1.2 Relevant diseases and conditions

The 3C Patch is intended to treat hard-to-heal diabetic foot ulcers that have not responded to standard wound care. Hard-to-heal diabetic foot ulcers are often considered as those that have not shown substantial healing (reduction in size by 50% or more) after 4 weeks of treatment.

It is estimated that more than 3.9 million people are living with a diagnosis of diabetes in the UK (2018 to 2019, Diabetes UK). Foot complications such as diabetic foot ulcers are common in people with diabetes. According to Diabetes UK, it is estimated that 1 in 20 people with diabetes will develop a foot ulcer each year, and of these, more than 1 in 10 will ultimately need amputation. Even after the resolution of a foot ulcer, subsequent foot ulcers are common. Roughly 40% of people with a foot ulcer will have a recurrence within 1 year after ulcer healing, almost 60% within 3 years, and 65% within 5 years (Armstrong et al. 2017).

Foot problems in people with diabetes have a significant financial impact on the NHS. A study published in 2019 reported that during 2014 to 2015, between £837 million and £962 million was spent on managing foot ulcers or undertaking amputations in people with diabetes in England, representing 0.8% to 0.9% of the country's NHS budget. Ulceration equated to 90% of

expenditure, and data suggests it is associated with increased length of hospital stay (by around 8 days) compared to that for diabetes-related admissions without ulceration (Kerr et al. 2019).

1.3 Current management

The aims of treatment for diabetic foot ulcers are to dress and protect the ulcer, to prevent or treat any infection and to promote healing. NICE's guideline on the prevention and management of diabetic foot problems recommends that diabetic foot ulcers are assessed by a healthcare professional, who should record the size, depth and position of the ulcer and refer the person to a diabetic foot protection team for assessment of the wound.

The guideline also recommends that one or more of the following is offered to people as standard care for treating diabetic foot ulcers:

- Offloading (interventions to reduce the amount of weight placed on the foot)
- Control of foot infection
- Control of ischaemia (for example, surgery to bypass the blocked blood vessels to restore blood circulation to the affected area)
- Wound debridement (removal of dead or infected tissue or foreign objects from the wound)
- Wound dressings

NICE's medical technologies guidance on UrgoStart for treating diabetic foot ulcers and leg ulcers recommends that UrgoStart dressings should be considered as an option for people with diabetic foot ulcers after any modifiable factors such as infection have been treated.

Negative pressure wound therapy may also be considered after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service. It is also recommended that clinical assessment and patient preference should inform dressing choices but that healthcare professionals should choose the lowest cost dressing that is likely to achieve the desired results.

NICE advice states that there is not enough evidence to determine if advanced dressings (such as alginate, film, foam, hydrocolloid and hydrogel dressings) are more clinically effective than conventional dressings for treating wounds. It also states that there is not currently robust evidence supporting the use of antimicrobial dressings (such as silver, iodine or honey) over non-medicated dressings for treating chronic wounds. Patients with diabetic foot ulcers are treated in community, hospital and primary care settings.

1.4 Regulatory status

3C Patch device received a CE mark in December 2009 (updated in December 2019) as a Class IIa device. The 3CP centrifuge is CE marked as a laboratory centrifuge.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Heals more wounds and reduces wound healing time
- Helps to avoid wound-related complications, including amputation and infection, reducing the need for further treatment
- Improved quality of life through reduced ulcer duration and the avoidance of complications, enabling people to return to activities of daily living sooner and avoid long term reduction in quality of life

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

- Reduced demand for ulcer care, across all care settings
- Reduced need for follow-on treatment including amputation and associated rehabilitation
- Reduced overall costs associated with treating hard-to-heal diabetic foot ulcers

2 Decision problem

Population	People with diabetic foot ulcers that are not healing despite standard wound care
Intervention	3C Patch

Comparator(s)	Standard conventional and advanced wound dressings for diabetic foot ulcers, including UrgoStart. Standard care is likely to vary depending on the characteristics of the wound (size, depth, and position) and stage of healing.

Outcomes	The outcome measures to consider include:
	• measures of treatment effectiveness and wound healing, for example:
	  ○ proportion of people with complete epithelialisation or healing
	  ○ time to complete epithelialisation or healing
	  ○ change in ulcer area
	• complications related to non-healing wounds, for example:
	  ○ incidence of wound-related complications (including new infection)
	  ○ number of new amputations
	  ○ pain at ulcer location
	  ○ frequency and amounts of antibiotic or pain medication requirements
	• device-related adverse events
	• patient-reported outcomes, for example:
	  ○ patient tolerance and acceptability
	  ○ health related quality of life
	• measures of resource use
	  ○ total number of 3C Patch treatments needed
	  ○ frequency and total number of secondary dressing changes
	  ○ demand for NHS diabetic foot ulcer care – outpatient, community, primary care and inpatient care

Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	None identified.
Special considerations, including those related to equality	3C Patch requires blood to be taken weekly and may not be suitable for people who are unable to provide blood samples, including people with trypanophobia (fear of needles). 3C Patch is intended for people with diabetes. In some cases, diabetes can be considered a disability. People of South Asian, African and African Caribbean family origin are more at risk of diabetes, however there is no evidence that the prevalence of diabetic foot ulceration and amputation is higher in these subgroups than in the general population of people with diabetes in the UK. Disability and race are protected characteristics under the 2010 Equalities Act.

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable.	

3 Related NICE guidance

Published

- V.A.C. VERAFLO Therapy System for acute infected or chronic wounds that are failing to heal (2020) NICE medical technologies guidance MTG54
- Leg ulcer infection: antimicrobial prescribing (2020) NICE guideline NG152.
- Diabetic foot problems: prevention and management (2019) NICE guideline NG19.
- UrgoStart for treating diabetic foot ulcers and leg ulcers (2019) NICE medical technologies guidance MTG4.
- The MIST Therapy system for the promotion of wound healing (2011) NICE medical technologies guidance MTG5.

In development

NICE is developing the following guidance:

- Prontosan for acute and chronic wounds NICE medical technology guidance. Publication expected October 2021.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Association of British Clinical Diabetologists
- British Society for Paediatric Endocrinology and Diabetes
- Institute of Chiropodists and Podiatrists
- Primary Care Diabetes Society
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Surgeons
- Society of Chiropodists and Podiatrists
- Society of Vascular Nurses
- The College of Podiatry
- The Welsh Wound Innovation Initiative
- Tissue Viability Society
- Vascular Society of Great Britain & Ireland

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- British Skin Foundation (BSF)
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Foot in Diabetes UK
- InDependent Diabetes Trust
- Juvenile Diabetes Research Foundation
- Leg Ulcer Charity
- Leonard Cheshire disability
- Limbless Association
- MRSA Action UK
- Pressure Ulcers UK
- The Circulation Foundation
- The Lindsay Leg Club Foundation