NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

V.A.C. VERAFLO Therapy System for acute infected or chronic wounds that are failing to heal

1 Technology

1.1 Description of the technology

V.A.C. VERAFLO Therapy System (3M+KCI) combines negative pressure wound therapy (NPWT) and wound instillation with topical solutions, with the aim of promoting wound healing. Wound instillation is a controlled process in which topical solutions are slowly introduced to the wound bed where they remain for a defined period of time before being removed using negative pressure. Treatment is delivered in automated treatment cycles allowing wounds to be repetitively cleansed without the need for dressing removal.

V.A.C. VERAFLO therapy system consists of the following components:

- V.A.C. ULTA therapy unit – delivers V.A.C. VERAFLO therapy (NPWTi-d; Negative Pressure Wound Therapy with instillation and a dwell time)
- Exudate canister – single-patient use, disposable canister (500, or 1000ml) which collects exudate/fluid
- V.A.C. VERALINK Cassette – instillation cassette which connects the solution bag/bottle and dressing tubing to the V.A.C.ULTA unit
- V.A.C. VERAFLO Dressing Kit of clinician's choice (V.A.C VERAFLO dressing, V.A.C. VERAFLO CLEANSE dressing or V.A.C. VERAFLO CLEANSE CHOICE dressing). The V.A.C. VERAFLO Dressing Kits includes the appropriate dressing as well as V.A.C. VERAT.R.A.C. Pad

with tubin, V.A.C. Advanced Drape and 3M Cavilon No Sting Barrier Film.

- Manufacturer's approved topical wound solution of clinician's choice

The V.A.C. VERAFLO system can be used with a number of topical wound solutions and suspensions. Suitable solutions and suspensions should be those indicated for topical wound treatment in their instructions for use. They should also be compatible with V.A.C VERAFLO dressings and disposable components.

Before using the V.A.C. VERAFLO Therapy system, the V.A.C. VERAFLO dressing foam of the appropriate size is applied to the wound bed. A V.A.C. Advance Drape is then placed over the wound with a 3-cm margin to make sure there is full adhesion, with a small hole cut into the drape surface. The V.A.C. VERAT.R.A.C. Pad can then be attached to the drape, using a stabilisation layer to ensure complete contact. The pad is then connected to the V.A.C. ULTA therapy unit. This collects fluid and substances produced by the body in response to tissue damage in the wound into a single-use 500-ml or 1,000-ml canister. The V.A.C. ULTA therapy unit fill assist tool is used to determine and ensure an appropriate instillation volume has been applied and the SEAL CHECK leak detector feature allows the user to observe the dressing for leaks.

The V.A.C. VERAFLO Therapy system is applied by healthcare professionals in a hospital setting. Healthcare staff using the technology will need training provided by the company. The company provides online resources to reinforce the training

1.2 Relevant diseases and conditions

The V.A.C. VERAFLO Therapy system is used to treat acute infected or chronic wounds that do not respond to standard care and need additional therapy to promote healing and wound closure. The population who could potentially benefit from this technology is significant. It is estimated that over 2 million patients a year have treatment for a wound, 48% of which are

considered chronic. Guest et al. (2015) reported that 79% of acute wounds and 43% of chronic wounds heal within 12 months. Results from this study suggest that approximately 21% of acute wounds and 57% of chronic wounds may not respond to standard care and may need additional therapy.

1.3 Current management

There are a number of clinical situations that may result in acutely infected or chronic non-healing wounds, such as surgical site infections, diabetic foot problems and pressure ulcers, for which NICE has published recommendations and advice.

Care of acutely infected or chronic non-healing wounds is targeted towards promoting healing and minimising risk of further complications. If infection of the wound is suspected, a microbiological sample is taken and an antibiotic prescribed to treat the causative organisms. The wound is treated with regular cleansing and debridement followed by the application of a dressing. Hospital staff choose a dressing that will promote healing and manage exudate on a case-by-case basis. Some wounds are treated with negative pressure wound therapy. Chronic non-healing wounds typically need more advanced dressings. Patients may be referred to a specialist for multidisciplinary care and the need for this varies depending on the cause of the wound.

NICE has also issued guidance on the use of negative pressure wound therapy for the open abdomen, which recommends the use of NPWT in patients at risk of developing surgical site infections.

1.4 Regulatory status

V.A.C. VERAFLO Therapy system received a CE mark in March 2017 as a class II medical device. Each component part of the system including sterile foam dressing kits and tube sets, and electrically powered accessories are also individually CE marked.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Reduced wound healing time by combining the benefits of NPWT with automatically instilling solutions to remove infectious material
- Reduced number of surgical debridements, resulting in fewer painful procedures and possible general anaesthetics
- More patients leaving hospital with closed wounds allowing them to return to normal daily activities
- Reduced hospital length of stay

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

- Patients discharged more quickly
- Reduction in follow on treatment costs
- Overall reduction in staff and resource use

2 Decision problem

Population	Patients with acute infected or chronic wounds that are failing to heal
Intervention	The V.A.C. VERAFLO Therapy system
Comparator(s)	• Standard advanced wound dressings (e.g. hydrogel dressings, hydrocolloid dressing, capillary-acting dressings, alginate dressings) • Negative pressure wound therapy
Outcomes	The outcome measures to consider include: Clinical management outcomes: • Length of stay in hospital • Rates of partial and complete wound closure (which may vary depending on wound type, location, depth and size) • Mean time to partial or complete wound closure • Mean time to healing • Number of dressing changes • Number of follow on treatments and visits to hospital • Number of surgical debridements • Number of amputations or skin grafts • Staff time and use of other consumables • Colonisation with antimicrobial resistant pathogens • Antibiotic use

	Patient outcomes: • Health-related quality of life • Patient satisfaction and acceptability • Patient-related outcomes such as pain scores • Device-related adverse events.	
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	• Diabetic ulcers • Pressure ulcers • Surgical site infections • Venous leg ulcers • Wounds containing prosthetic implants	
Special considerations, including those related to equality	People who are older or physically disabled are more likely to suffer chronic and complex wounds. People with certain family origins are more prone to poor wound healing due to increased risk of diabetes. Age, disability, and race are protected characteristics.	
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

Pathways:

- Pressure ulcers overview (2019) NICE Pathway
- Prevention and control of healthcare-associated infections overview (2019) NICE Pathway
- Foot care for people with diabetes overview (2019) NICE Pathway
- Skin conditions overview (2019) NICE Pathway

Guidelines:

- Surgical site infections: prevention and treatment (2019) NICE guideline NG125
- Pressure ulcers: prevention and management (2014) NICE guideline CG179
- Diabetic foot problems: prevention and management (2015) NICE guideline NG19. Last updated: January 2016

Guidance:

- UrgoStart for treating diabetic foot ulcers and leg ulcers (2019) NICE medical technologies guidance 42
- PICO negative pressure wound dressings for closed surgical incisions (2019) NICE medical technologies guidance 43
- Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers (2019) NICE medical technologies guidance 40
- The Debrisoft monofilament debridement pad for use in acute or chronic wounds (2014) NICE medical technologies guidance 17. Last updated: March 2019
- moorLDI2-BI: a laser doppler blood flow imager for burn wound assessment (2011) NICE medical technologies guidance 2. Last updated: August 2017
- Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers (2014) NICE medical technologies guidance 20

- The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury (2014) NICE medical technologies guidance 21
- The MIST Therapy system for the promotion of wound healing (2011) NICE medical technologies guidance 5
- Negative pressure wound therapy for the open abdomen (2013) NICE interventional procedures guidance 467

Advice:

- Prevena incision management system for closed surgical incisions (2019) NICE medtech innovation briefing 173
- SEM Scanner for pressure ulcer prevention (2019) NICE medtech innovation briefing 182
- EpiFix for chronic wounds (2018) NICE medtech innovation briefing 139
- TopClosure Tension Relief System for wound closure (2017) NICE medtech innovation briefing 97
- Woundchek Protease Status for assessing elevated protease status in chronic wounds (2016) NICE medtech innovation briefing 83
- Mersey Burns for calculating fluid resuscitation volume when managing burns (2016) NICE medtech innovation briefing 58
- The Juxta CURES adjustable compression system for treating venous leg ulcers (2015) NICE medtech innovation briefing 25
- Oxyzyme and Iodozyme 2-layer hydrogel wound dressings with iodine for treating chronic wounds (2014) NICE medtech innovation briefing 11
- The Versajet II hydrosurgery system for surgical debridement of acute and chronic wounds and burns (2014) NICE medtech innovation briefing 1

Quality standards:

- Pressure ulcers (2015) NICE quality standard 89

In development

NICE is developing the following guidance:

- Diabetic foot infection: antimicrobial prescribing. NICE guideline. Publication expected October 2019
- Leg ulcer infection: antimicrobial prescribing. NICE guideline. Publication expected February 2020
- Diabetic foot ulcers - new treatments. NICE guideline. Publication date TBC

4 External organisations

4.1 Professional

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

- Association of Breast Surgery
- Association of Surgeons of Great Britain and Ireland
- British Association for Surgery of the Knee
- British Association of Paediatric Surgeons
- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Obesity and Metabolic Surgery Society
- British Obesity Surgery Society
- Royal College of Obstetricians and Gynaecologists
- Royal College of Surgeons
- Society of Vascular Nurses
- Surgical Dressing Manufacturers Association
- Society for Cardiothoracic Surgery in GB and Ireland
- British Association of Aesthetic Plastic Surgeons
- Primary Care Diabetes Society

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
- Leg Ulcer Charity
- Pressure Ulcers UK

- Leonard Cheshire disability
- British Obesity Surgery Patients Association (BOSPA)
- Children's Burn Trust (CBT)
- Colostomy Association
- Crohn’s and Colitis UK (NACC)
- Diabetes UK
- Foot in Diabetes UK
- IA (Ileostomy and Internal Pouch Support Group)