NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Prontosan for acute and chronic wounds

1 Technology

1.1 Description of the technology

Prontosan (B Braun) is a range of topical solutions and gels used for cleansing and moistening acute and chronic wounds. Prontosan is available as:

- Prontosan Wound Irrigation Solution, used for wound irrigation or applied to gauze as a soak, 350ml bottle, 40ml single-use pods and 1,000ml bottle for instillation.
- Prontosan Wound Gel, applied to the wound bed during dressing changes after wound cleansing and before application of secondary dressing. The 30ml bottle is suitable for use in deep and tunnelling wounds, wound cavities and difficult to access wounds.
- Prontosan Wound Gel X (extra thick gel), 50g or 250g tube, applied to the wound bed during dressing changes, after wound cleansing and before application of secondary dressing. It is suitable for use in flat or larger surface area wounds such as leg ulcers.

The solution and gels contain an antimicrobial polyhexanide (0.1% polyhexamethylene biguanide) and a betaine surfactant (0.1% undecylenamidopropyl betaine). The company claim that Prontosan is the only wound cleansing solution or gel that contains these 2 active ingredients which work in combination to disrupt and prevent biofilm from the wound bed as well as cleansing and removing slough, devitalised tissue and other wound debris.

1.2 Relevant diseases and conditions

Prontosan is intended for use in acute and chronic wounds only when they require cleansing. The types of wounds that may be encountered include:

- Acute non-infected and infected wounds such as trauma wounds (skin lacerations, bites, cuts or crush injuries) and post-operative wounds.
- Chronic non-infected and infected wounds including pressure ulcers, leg ulcers and diabetic foot ulcers.
- Thermal, chemical and post-radiation wounds including burns.

The population who may benefit from this technology is large. It is estimated that in the UK, over 2 million people per year have wounds that require treatment. A cohort analysis of 1,000 NHS patients that have wounds suggested that about 39% of wounds do not heal within the first year and may need additional therapy.

1.3 Current management

Current treatment options for cleansing acute and chronic wounds include sterile saline or water. Care of acute or chronic non-healing wounds aims to improve wound condition, promote healing and minimise the risk of further complications. If the wound is suspected of being infected, a microbiological sample is usually taken and an antibiotic prescribed to treat the organism causing the infection. The wound is treated with regular cleansing and debridement (autolytic, mechanical, or surgical, as required by the wound) and then a dressing is applied. An appropriate dressing is selected to promote healing and manage exudate on a case-by-case basis. Chronic wounds may be treated with advanced dressings that usually work by simple physical or chemical means, typically by controlling moisture levels (for example, alginate, film, foam, hydrocolloid and hydrogel dressings).

The following publications have been identified as relevant to this care pathway: NICE's guidelines on surgical site infections, diabetic foot problems and pressure ulcers.

1.4 Regulatory status

Prontosan received a CE mark in February 2009 as a class III medical device. The different sizes and preparations of Prontosan are covered under the CE mark.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Quicker wound healing and fewer wound care service visits needed.
- Improved quality of life.
- Improved wound bed condition: reduced pain, wound exudate, odour, and slough.
- Reduced infection and markers of infection.

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

- Reduced need for wound care services (including community wound care) and associated costs because of fewer dressing changes and faster healing time.
- Reduced need for antibiotics, antimicrobial dressings and pain medication.

2 Decision problem

Population	Adults and children with acute or chronic wounds
Intervention	• Prontosan Wound Irrigation Solution • Prontosan Wound Gel • Prontosan Wound Gel X
Comparator(s)	• Saline • Water • Ringers solution
Outcomes	The outcome measures to consider include: • Proportion of wounds with complete closure • Time to complete wound closure • Other outcomes related to wound characteristics including wound size, volume and area • Number of dressing changes and use of antimicrobial dressings and other consumables • Incidence of wound infection evidenced by

	○ Adverse events and/or use of antibiotics (related to wound infection) ○ Reduction in clinical signs of infection • Changes to wound bed condition including slough, exudate, granulation and oedema • Staff time • Antibiotic use • Analgesic use • Length of hospital stay • Number of follow on treatments including GP, nurse and hospital visits • Number of surgical debridement procedures • Number of amputations or skin grafts • Colonisation with antimicrobial resistant pathogens Patient and carer related outcomes: • Health-related quality of life • Patient-related outcomes such as pain scores, discomfort and wound odour, or level of satisfaction • Carer's level of satisfaction • Mortality rates • 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	• Burns • Diabetic foot ulcers • Leg ulcers • Pressure ulcers • Post-operative wounds (with and without surgical site infection) • Trauma wounds • Infected wounds of any aetiology • Recurrent infections • Wound duration • Wound size • Children or adolescents
Special considerations, including those	Older people, people with diabetes, people with restricted mobility and people with darker skin tones are more likely to have chronic

related to equality	or non-healing wounds. 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	Category 1 pressure ulcers are identified by visual assessment of a non-blanching area of redness. In people with darker skin tones, it may not be possible to identify pressure ulcers by visual assessment. People with certain family origins are also more prone to poor wound healing due to receiving poorer quality care and have an increased risk of developing conditions that may cause poor healing outcomes (such as diabetes).	

3 Related NICE guidance

Published

- Leg ulcer infection: antimicrobial prescribing. (2020) NICE guideline.
- Surgical site infections: prevention and treatment (2020) NICE guideline NG125
- Diabetic foot infection: antimicrobial prescribing. (2019) NICE guideline.
- Diabetic foot problems: prevention and management (2015) NICE guideline NG19. Last updated: January 2016
- Pressure ulcers: prevention and management (2014) NICE guideline CG179

In development

NICE is developing the following guidance:

- 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 for Perioperative Practice
- Association of Breast Surgery
- Association of Surgeons of Great Britain and Ireland
- British Association of Paediatric Surgeons
- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Obesity and Metabolic Surgery Society
- British Obesity Surgery Society
- British Pain Society
- Community Practitioners' & Health Visitors Association
- Primary Care Diabetes Society
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal college of Surgeons
- Society of Vascular Nurses
- Surgical Dressing Manufacturers Association
- The Vascular Society
- Tissue Viability Society