

## PUBLIC SUMMARY DOCUMENT

**Product:** Prontosan Wound Spray 75ml

**Applicant:** B Braun Australia Pty Ltd

**Date of SPAP Meeting:** 28 April 2020

### 1. Proposed Listing on the Stoma Appliance Scheme

The applicant, B Braun Australia Pty Ltd, sought listing of the Prontosan Wound Spray 75ml on the Stoma Appliance Scheme (SAS) Schedule. The product was proposed for listing at a unit price of \$9.95, with a maximum monthly quantity of one unit.

### 2. Comparator

The applicant did not nominate a comparator product, or a subgroup for the proposed product.

### 3. Background

This was the Stoma Product Assessment Panel's (the Panel) first consideration of this product.

### 4. Clinical Place for the Product

The proposed product is a wound spray that can be used by ostomates who may have a wound around the stoma.

### 5. Panel Comment

#### *Clinical Analysis*

The Panel noted the product is an antibacterial wound spray suitable for application around a wound that requires treatment. The Panel also noted the applicant did not nominate a comparator product.

The Panel also noted, the applicant submitted studies to support their application, however the information provided did not include ostomates with a peristomal wound.

The Panel agreed the applicant had not provided sufficient clinical evidence to support the application. The Panel also agreed that no specific clinical use of the product in the relevant patient population had been demonstrated in the application.

#### *Economic Analysis*

Not undertaken.

#### *Financial Analysis*

Not applicable.

## **6. SPAP Recommendation**

The Panel recommended the application for the Prontosan Wound Spray 75ml be rejected due to inadequate clinical evidence to support the application.

## **7. Context for Decision**

The Panel helps decide whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. It considers submissions in this context. A Panel decision not to recommend listing or changes to a listing does not represent a final Panel view about the merits of a particular stoma product. A company can resubmit to the Panel following a decision not to recommend listing or changes to a listing. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Cabinet/Ministerial approval.

## **8. Applicant's Comment**

B Braun Australia Pty Ltd accepts and respects the Panel's decision.