

PUBLIC SUMMARY DOCUMENT

Product: Brava Protective Seal
Applicant: Coloplast Pty Ltd
Date of SPAP Meeting: 11 April 2016

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought listing of the Brava Protective Seal in subgroup 9(1) of the Stoma Appliance Scheme (SAS) Schedule. The product, including six variants, was proposed for listing at the benchmark unit price of \$4.532 with a maximum monthly quantity of 30 units.

2. Comparator

The applicant nominated Omnigon Cohesive Seal (SAS code 3672G) from Omnigon, which is currently listed in subgroup 9(1), as the comparator. This product is currently listed at the unit price of \$4.532.

3. Background

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

4. Clinical Place for the Product

The proposed product provides an alternative for users requiring a product to improve the seal around the stoma, protecting peristomal skin from corrosive output.

5. SPAP Comment

Clinical Analysis

The Panel noted the proposed product is a shape-able adhesive seal and is intended to provide a barrier between the stoma and the ostomy base plate. The Panel also noted that the applicant states that the product can be applied to the peristomal skin surrounding the stoma to form a barrier against leakage. No clinical data was presented.

Economic Analysis

Not undertaken.

Financial Analysis

Listing of this product is recommended on a cost minimisation basis compared with the notional benchmark product in subgroup 9(1) of the SAS Schedule. It is therefore unlikely that there would be any budgetary impact for the SAS as a consequence of listing this product under the conditions requested by the applicant.

6. SPAP Recommendation

The SPAP recommended that the Brava Protective Seal, including six variants, be listed in subgroup 9(1) of the SAS Schedule, at a unit price of \$4.532, with a maximum monthly quantity of 30 units.

However, the Panel noted that all recommendations for products to be listed in Group 9 of the SAS Schedule may be subject to change as a result of the outcomes from the Group 9 Review. The outcomes of the Group 9 Review are expected in 2016.

7. Context for Decision

The SPAP helps decide whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. It considers submissions in this context. An SPAP decision not to recommend listing or changes to a listing does not represent a final

SPAP view about the merits of a particular stoma product. A company can resubmit to the SPAP following a decision not to recommend listing or changes to a listing. The SPAP is an advisory committee and as such its recommendations are non-binding on Government. All SPAP recommendations are subject to Cabinet/Ministerial approval.

8. Applicant's Comment

Coloplast agrees with SPAP's recommendation.