

Public summary document

Product: Omnigon BBraun Flexima Active

Applicant: Omnigon Pty Ltd

Date of SPAP Meeting: 26 April 2022

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon Pty Ltd, sought listing of the Omnigon BBraun Flexima Active in subgroup 2(b) of the Stoma Appliance Scheme (SAS) Schedule. The product (one variant) was proposed for listing at a unit price of \$6.373, with a maximum monthly quantity of 30 units.

2. Comparator

The applicant nominated Omnigon BBraun Flexima Active (SAS Code 80142B) as the comparator. The product (8 variants with shallow convexity) is currently listed in subgroup 2(b) of the SAS Schedule at the unit price of \$6.373, with a maximum monthly quantity of 30 units.

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 an alternative for users requiring a one-piece drainable pouch with a convex baseplate.

5. Clinical Analysis

The Panel noted that the proposed product is a replacement for the comparator, BBraun Flexima Active (SAS Code 80142B) and the sponsor Omnigon stated that no further clinical evidence is warranted due to the new product being similar to the comparator.

6. Economic Analysis

The Panel noted that the proposed product is a replacement for the comparator, BBraun Flexima Active (SAS Code 80142B) and the sponsor Omnigon stated that no economic analysis is required as the product is non-inferior to its comparator and is priced at the benchmark for products in sub-group 2(b) of the SAS Schedule.

7. Financial Analysis

Listing of this product is unlikely to have a budgetary impact for the SAS.

8. SPAP Recommendation

The Panel recommended that the Omnigon BBraun Flexima Active be listed in subgroup 2(b) of the SAS Schedule with one variant, at the unit price of \$6.373, with a maximum monthly quantity of 30 units.

9. Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. Applications are considered in this context. Panel advice 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 advice 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 Government approval.

10. Applicant's Comment

The applicant noted the SPAP recommendation.