

PUBLIC SUMMARY DOCUMENT

Product: Omnigon Eakin Dot One Piece Soft Convex High Output

Applicant: Omnigon

Date of SPAP Meeting: 20 April 2021

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon sought listing of the Omnigon Eakin Dot One Piece Soft Convex High Output in subgroup 11(a) of the Stoma Appliance Scheme (SAS) Schedule. The proposed product, including two variants, was proposed for listing at a unit price of \$22.330, with a maximum monthly quantity of 20 units.

2. Comparator

The applicant nominated the Coloplast SenSura Mio One Piece High Output Soft Convex (SAS code 80155Q) as the comparator. The product is currently listed in subgroup 11(a) of the SAS Schedule at the unit price of \$22.330, with a maximum monthly quantity of 20 units. The Stoma Product Assessment Panel (SPAP) accepted this product as an acceptable comparator

3. Background

This was the SPAP's first consideration of this product.

4. Clinical Place for the Product

The proposed product provides an alternative for users requiring a high output collection bag.

5. SPAP Comment

Clinical Analysis

The Panel noted the proposed product is considered to be equivalent to products currently available at the benchmark price in subgroup 11(a).

The Panel also noted that the applicant states the volunteers took part in a clinical evaluation of the Eakin Dot Piece Convex High Output drainable pouch, however no data was provided to support this claim.

Economic Analysis

Not undertaken.

Financial Analysis

Listing of this product is recommended on a cost-minimisation basis compared to products currently listed in subgroup 11(a) 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.

6. SPAP Recommendation

The SPAP recommended that the Omnigon Eakin Dot One Piece Soft Convex High Output, including two variants be listed in subgroup 11(a) of the SAS Schedule at the unit price of \$22.330, with a maximum monthly quantity of 20 units.

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. A 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

Omnigon agrees with the SPAP's recommendation.