

PUBLIC SUMMARY DOCUMENT

Product: Omnigon Flexima 3S
Applicant: Omnigon
Date of SPAP Meeting: 22 October 2019

1. Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of four variants no longer available, from the current listing of the Omnigon Flexima 3S (SAS Code 80078P) in subgroup 4(c) of the Stoma Appliance Scheme (SAS) Schedule. The product, including nine variants, is currently listed at a unit price of \$5.84, with a maximum monthly quantity of 20 units.

2. Substitute products

The nominated substitute products are variants in the Omnigon Flexima 3S (SAS Code 80078P). The product, including four variants, is currently listed in subgroup 4(c), of the SAS Schedule at a unit price of \$5.84, with a maximum monthly quantity of 20 units.

Variants to be deleted

Product Code	Description
937420	45mm ring, medium convexity, hexagon, pre-cut 20mm
937535	55mm ring, medium convexity, hexagon, pre-cut 35mm
937640	65mm ring, medium convexity, hexagon, pre-cut 40mm
937645	45mm ring, medium convexity, hexagon, pre-cut 45mm

Nominated substitute – SAS Code 80078P - Omnigon Flexima 3S

Product Code	Description
937415	no belt loop, mechanical coupling with lock, 45mm ring, floating flange, 1.3mm, hydrocolloid baseplate, medium convexity, rigid convex ring, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, release tabs, 26mm,
937515	No belt loop, mechanical coupling with lock, 55mm ring, floating flange, 1.3mm, hydrocolloid baseplate, medium convexity, rigid convex ring, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, release tabs, 36mm,
937615	No belt loop, mechanical coupling with lock, 65mm ring, floating flange, 1.3mm, hydrocolloid baseplate, medium convexity, rigid convex ring, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, release tabs, 46mm

3. Background

This product was first listed on the SAS Schedule in April 2016.

4. Clinical Place for the Product

The proposed substitute product provides an alternative for users requiring a two-piece baseplate with mechanical coupling-convex.

Financial Analysis

The deletion of four variants is recommended. Substitute products are currently listed in subgroup 4(c), of the SAS Schedule at the same cost and maximum monthly quantity. It is therefore unlikely that there would be any budgetary impact for the SAS as a consequence of deleting this product.

5. SPAP Recommendation

The SPAP recommended the deletion of four variants from the product range for Omnigon Flexima 3S (SAS Code 80078P) listed in subgroup 4(c), of the SAS Schedule at the unit price of \$5.84, with a maximum monthly quantity of 20 units.

The SPAP also noted that Omnigon is to advise Stoma Associations, ostomates, Stomal Therapy Nurses and ACSA of the deletion. A period of approximately six months from the SPAP recommended date (22 October 2019) should be given to allow users of the product to seek a suitable alternative and to enable Stoma Associations to manage their stock levels.

6. 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.

7. Applicant's Comment

Omnigon agrees with the SPAP's recommendation.