PUBLIC SUMMARY DOCUMENT

Product: Omnigon BBraun Flexima Active

Applicant: Omnigon

Date of SPAP Meeting: 20 October 2020

1. Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of four variants from the current listing of Omnigon BBraun Flexima Active (SAS Code 80142B) in subgroup 2(b) of the Stoma Appliance Scheme (SAS) Schedule. Omnigon has advised the products were never manufactured. The product, including 11 variants, is currently listed at a unit price of \$6.373, with a maximum monthly quantity of 30 units.

2. Substitute products

The nominated substitute products are variants in the same range, Omnigon BBraun Flexima Active (SAS Code 80142B).

Variants to be deleted

| Product Code | Description |
|--------------|---|
| 4620715 | Protected single carbon filter, opaque with fabric cover on both sides, medium, 560ml, low headspace, integrated closure, belt loops on each side of baseplate, 0.8mm, hydrocolloid baseplate, shallow convexity, firm baseplate material, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, no release tabs, 35mm. |
| 4620716 | Protected single carbon filter, opaque with fabric cover on both sides, medium, 560ml, low headspace, integrated closure, belt loops on each side of baseplate, 0.8mm, hydrocolloid baseplate, shallow convexity, firm baseplate material, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, no release tabs, 45mm. |
| 4622715 | Protected single carbon filter, transparent with fabric cover on both sides including viewing window, medium, 560ml, low headspace, integrated closure, belt loops on each side of baseplate, 0.8mm, hydrocolloid baseplate, shallow convexity, firm baseplate material, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, no release tabs, 35mm. |
| 4621716 | Protected single carbon filter, transparent with fabric backing, medium, 560ml, low headspace, integrated closure, belt loops on each side of baseplate, 0.8mm, hydrocolloid baseplate, shallow convexity, firm baseplate material, hydrocolloid self-adhesive, standard wear, hexagon, cut-to-fit, 15mm, no release tabs, 45mm. |

Nominated substitute – SAS Code 80142B

| Product Code | Description |
|--------------|---|
| 4622716 | Protected single carbon filter, transparent with fabric |
| | backing, medium, 560ml, low headspace, integrated closure, |
| | belt loops on each side of baseplate, 0.8mm, hydrocolloid |
| | baseplate, shallow convexity, firm baseplate material, |
| | hydrocolloid self-adhesive, standard wear, hexagon, cut-to- |
| | fit, 15mm, no release tabs, 45mm. |
| 4621715 | Protected single carbon filter, transparent with fabric |
| | backing, medium, 560ml, low headspace, integrated closure, |
| | belt loops on each side of baseplate, 0.8mm, hydrocolloid |
| | baseplate, shallow convexity, firm baseplate material, |
| | hydrocolloid self-adhesive, standard wear, hexagon, cut-to- |
| | fit, 15mm, no release tabs, 35mm. |

3. Background

This product was first listed on the SAS Schedule in May 2017.

4. Clinical Place for the Product

The proposed substitute product provides an alternative for users requiring a One-Piece Drainable pouch with Convex Baseplate.

Financial Analysis

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

5. Panel Recommendation

The Panel recommended the deletion of four variants from the product range for Omnigon BBraun Flexima Active (SAS Code 80142B) in subgroup 2(b) of the SAS Schedule at the unit price of \$6.373, with a maximum monthly quantity of 30 units.

The Panel 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 date of the Panel's recommendation (20 October 2020) 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 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.

7. Applicant's Comment

Omnigon agrees with the Panel's recommendation.