



# Stoma Product Assessment Panel

## Public Summary Documents

### B. Braun Australia Pty Ltd – 12 November 2024

#### Contents

B. Braun Australia Pty Ltd Flexima® Active Soft Convex High Flow – BB#01NOVEMBER2024	.2
B. Braun Australia Pty Ltd Flexima® Active Soft Convex Uro – BB#02NOVEMBER2024	.....3
B. Braun Australia Pty Ltd Ally® Wafer Extenders – BB#03NOVEMBER2024	.....4
B. Braun Australia Pty Ltd Ally® Rings – BB#04NOVEMBER2024	.....5
B. Braun Australia Pty Ltd Ally® Powder– BB#05NOVEMBER2024	.....6
B. Braun Australia Pty Ltd Ally® Paste – BB#06NOVEMBER2024	.....7
B. Braun Australia Pty Ltd Flexima® High Flow – BB#07NOVEMBER2024	.....8
B. Braun Australia Pty Ltd Deletion Requests – November 2024	.....10



## B. Braun Australia Pty Ltd Flexima® Active Soft Convex High Flow – BB#01NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia, sought listing of B. Braun Australia Pty Ltd Flexima® Active Soft Convex High Flow in subgroup 11(a) of the Stoma Appliance Scheme (SAS) Schedule.

The product, including one variant, was proposed for listing at a unit price of \$22.330, with a pack size of 10 units and a maximum monthly quantity of 20 units.

### Comparator

The applicant nominated Hollister Modema Flex Soft Convex High Output (80221E) as the comparator. The comparator product (6 variants) is currently listed in subgroup 11(a) of the SAS Schedule at the unit price of \$22.330, with a pack size of 10 units and a maximum monthly quantity of 20 units.

### Background

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

### Clinical Analysis

The proposed product provides an alternative for users requiring a fistulae product for a high output stoma or fistula. The Panel agreed the proposed product is clinically equivalent to other products available in subgroup 11(a).

### Economic and Financial Analysis

The Panel noted that the listing of this new product at the same price and the same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

### Panel Recommendation

The Panel recommended the B. Braun Australia Pty Ltd Flexima® Active Soft Convex High Flow be listed in subgroup 11(a) of the SAS Schedule with one variant, at the unit price of \$22.330, with a pack size of 10 units and a maximum monthly quantity of 20 units.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Flexima® Active Soft Convex Uro – BB#02NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia, sought listing of an additional 2 variants of B. Braun Australia Pty Ltd Flexima® Active Soft Convex Uro in subgroup 3(b) of the Stoma Appliance Scheme (SAS) Schedule. The additional variants were proposed for listing at a unit price of \$6.373, with a pack size of 10 units and maximum monthly quantity of 30 units.

### Comparator

The applicant nominated B. Braun Australia Pty Ltd Flexima® Active Soft Convex Uro (80165F) as the comparator. The comparator product (2 variants) is currently listed in subgroup 3(b) of the SAS Schedule at a unit price of \$6.373, with a pack size of 10 units and a maximum monthly quantity of 30 units.

### Background

This application was to add 2 variants to the existing product range of B. Braun Australia Flexima Active Soft Convex Uro (SAS code 80165F).

### Clinical Analysis

The proposed additional variants provide alternatives for users requiring a one-piece urostomy pouch with a convex baseplate. The Panel noted that this application is seeking to add 2 variants to the existing product range to include a pre-cut pouch with no filter and a non-return valve and tap.

### Economic and Financial Analysis

The Panel noted that the listing of 2 additional variants of this product at the same price and same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

### Panel Recommendation

The Panel recommended 2 new variants of the B. Braun Australia Pty Ltd Flexima® Active Soft Convex Uro be listed in subgroup 3(b) of the SAS Schedule, at a unit price of \$6.373, with a pack size of 10 units and a maximum monthly quantity of 30 units. The product codes of the new variants are to be listed under the existing SAS code 80165F.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Ally® Wafer Extenders – BB#03NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia, sought listing of B. Braun Australia Pty Ltd Ally® Wafer Extenders in subgroup 9(a) of the Stoma Appliance Scheme (SAS) Schedule. The product, including one variant, was proposed for listing at a unit price of \$1.458, with a pack size of 20 units and a maximum monthly quantity of 60 units.

### Comparator

The applicant nominated Coloplast Brava Elastic Tape (3897D) as the comparator. The comparator product (4 variants) is currently listed in subgroup 9(a) of the SAS Schedule at the unit price of \$1.458, with a pack size of 20 units and a maximum monthly quantity of 60 units.

### Background

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

### Clinical Analysis

The proposed product provides an alternative for users requiring an adhesive barrier. The Panel noted this product is gentle on the skin, low profile and contours well to different body shapes which enables extended wear time and secure wearability.

### Economic and Financial Analysis

The Panel noted that the listing of this new product at the same price and the same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

### Panel Recommendation

The Panel recommended the B. Braun Australia Pty Ltd Ally® Wafer Extenders be listed in subgroup 9(a) of the SAS Schedule with one variant, at the unit price of \$1.458, with a pack size of 20 units and a maximum monthly quantity of 60 units.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Ally® Rings – BB#04NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia, sought listing of B. Braun Australia Pty Ltd Ally® Rings in subgroup 9(l) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 3 variants, was proposed for listing at a unit price of \$4.532, with a pack size of 10 units and a maximum monthly quantity of 30 units.

### Comparator

The applicant nominated ConvaTec Stomahesive Ostomy Seal (80008Y) as the comparator. The comparator product (3 variants) is currently listed in subgroup 9(l) of the SAS Schedule at the unit price of \$4.532, with a pack size of 10 units and a maximum monthly quantity of 30 units.

### Background

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

### Clinical Analysis

The proposed product provides an alternative for users requiring a barrier seal. The Panel noted the product is mouldable, easy to use and is available in a range of sizes.

### Economic and Financial Analysis

The Panel noted that the listing of this new product at the same price and the same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

### Panel Recommendation

The Panel recommended the B. Braun Australia Pty Ltd Ally® Rings be listed in subgroup 9(l) of the SAS Schedule with 3 variants, at the unit price of \$4.532, with a pack size of 10 units and a maximum monthly quantity of 30 units.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Ally® Powder– BB#05NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia, sought listing of B. Braun Australia Pty Ltd Ally® Powder in subgroup 9(j) of the Stoma Appliance Scheme (SAS) Schedule. The product, including one variant, was proposed for listing at a unit price of \$8.700, with a pack size of one unit and a maximum monthly quantity of 2 units.

### Comparator

The applicant nominated Hollister Premium Powder (3556E) as the comparator. The comparator product (one variant) is currently listed in subgroup 9(j) of the SAS Schedule at the unit price of \$8.697, with a pack size of one unit and a maximum monthly quantity of 2 units.

### Background

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

### Clinical Analysis

The proposed product provides an alternative for users requiring an ostomy powder. The Panel noted the product is easy to use and is a useful product designed to absorb moisture on peristomal skin.

### Economic and Financial Analysis

The Panel noted that the listing of this new product at the same price and the same maximum monthly quantity as currently listed products in the same subgroup is expected to result in the same cost to the SAS.

### Panel Recommendation

The Panel recommended the B. Braun Australia Pty Ltd Ally® Powder be listed in subgroup 9(j) of the SAS Schedule with one variant, at the unit price of \$8.700, with a pack size of one unit and a maximum monthly quantity of 2 units.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Ally® Paste – BB#06NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia, sought listing of B. Braun Australia Pty Ltd Ally® Paste in subgroup 9(j) of the Stoma Appliance Scheme (SAS) Schedule. The product, including one variant (80g), was proposed for listing at a unit price of \$15.040 (\$0.188 per gram), with a pack size of one unit and a maximum monthly quantity of 2 units.

### Comparator

The applicant nominated Coloplast Brava Paste (80028B) as the comparator. The comparator product (one variant 60g) is currently listed in subgroup 9(j) of the SAS Schedule at the unit price of \$11.280 (\$0.188 per gram), with a pack size of one unit and a maximum monthly quantity of 3 units.

### Background

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

### Clinical Analysis

The proposed product provides an alternative for users requiring an ostomy paste. The Panel noted this product is a useful alternative for ostomates who may experience difficulty in applying a seal.

### Economic and Financial Analysis

The Panel noted that the listing of this new product will be at the same price per gram as the comparator product (\$0.188), but with a larger volume (80g vs 60g) and a lower maximum monthly quantity (2 units vs 3 units). The cost to the SAS for the maximum monthly quantity will be \$30.080 compared to \$33.840 for the comparator product. It is expected the addition of this product will have a budgetary impact with an estimated save to the SAS, which will be confirmed by the Department of Finance.

### Panel Recommendation

The Panel recommended the B. Braun Australia Pty Ltd Ally® Paste be listed in subgroup 9(j) of the SAS Schedule with one variant, at the unit price of \$15.040, with a pack size of one unit and a maximum monthly quantity of 2 units.

### Context for Recommendation

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy in Australia. Applications are considered in this context. The Panel is an advisory committee and its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Flexima® High Flow – BB#07NOVEMBER2024

### Proposed Listing on the Stoma Appliance Scheme

The applicant, B. Braun Australia Pty Ltd, sought to change the product name, subgroup, SAS code, price and maximum quantity of 2 variants of the B. Braun Australia Pty Ltd Flexima® Roll' Up Flat in subgroup 2(a) of the Stoma Appliance Scheme (SAS) Schedule. The proposed product, including 2 variants, is currently listed on the SAS Schedule under SAS code 9914T at a unit price of \$4.674, with a pack size of 30 units and a maximum monthly quantity of 30 units.

The applicant requested to change the product name of the 2 variants (42970P and 42971P) from B. Braun Australia Pty Ltd Flexima® Roll' Up Flat to B. Braun Australia Pty Ltd Flexima® High Flow.

The applicant requested to list the newly named variants under a new SAS code in subgroup 11(a) at a unit price of \$16.206, with a pack size of 30 and annual quantity of 240 units.

### Comparator

The applicant nominated Coloplast SenSura Mio One Piece High Output Flat (80133M) as the comparator. The comparator product (4 variants) is currently listed in subgroup 11(a) of the SAS Schedule at the unit price of \$16.206, with a pack size of 10 and a maximum monthly quantity of 20 units.

### Background

The B. Braun Australia Pty Ltd Flexima® Roll' Up Flat was first listed on the SAS Schedule in subgroup 2(a) on 1 April 2016. This is the Stoma Product Assessment Panel's (the Panel) second consideration of this product, but its first consideration of the product for listing in subgroup 11(a).

### Clinical Analysis

The Panel acknowledged the product is designed for use with a high flow stoma or fistula and would be more appropriately listed in subgroup 11(a). However, the sponsor did not provide appropriate evidence to support the product's listing in subgroup 11(a). The Panel questioned the clinical equivalency compared to other products listed in the same subgroup. The Panel also noted the pouch cap on the product sample appeared insecure, and questioned whether this would provide sufficient protection noting output material can be irritating to the skin.

### Economic and Financial Analysis

The Panel noted that the sponsor was seeking listing of the product in subgroup 11(a), at a higher price and maximum quantity than its current listing in subgroup 2(a), but at the same price and maximum quantity as other products in subgroup 11(a).





Should listing of this product be recommended in the future, the likely budgetary impact for the SAS would be dependent on the agreed price per unit and maximum quantity in comparison to other products listed in the same group and subgroup.

#### [Panel Recommendation](#)

The Panel deferred the application for B. Braun Australia Pty Ltd Flexima® High Flow to be listed in subgroup 11(a) of the SAS Schedule with 2 variants, at the unit price of \$16.206, with a pack size of 30 units and a maximum annual quantity of 240 units.

The Panel requested B. Braun provide additional evidence to determine that the product is clinically equivalent to other products in subgroup 11(a). The Panel will consider any new information at the next Panel meeting.

#### [Context for Recommendation](#)

The Panel provides advice on whether stoma products should be subsidised and, if so, the conditions of their subsidy 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. An applicant can resubmit to the Panel following advice not to recommend listing or changes to a listing.

#### [Applicant's Comment](#)

The applicant noted the recommendation.



## B. Braun Australia Pty Ltd Deletion Requests – November 2024

### Proposed Deletions on the Stoma Appliance Scheme

The applicant, B. Braun Australia Pty Ltd, sought the deletion of the following listings:

Application ID	Group ID	SAS Code	Brand Name	Pack Size	Max Qty	Unit Price	Total company codes	Company codes for deletion
BB#08	2a	9914T	B. Braun Australia Pty Ltd Flexima® Roll' Up Flat	30	30m	\$4.674	12	42970P 42971P

### Financial analysis

Substitute products are currently listed in the same subgroup at the same cost and maximum quantity. It is unlikely that there would be any budgetary impact for the SAS as a consequence of deleting the products.

### Recommendation

As these were administrative changes, these applications were considered by the Panel secretariat in line with the SAS *Application and Assessment Guidelines*. The Panel secretariat noted there are equivalent products remaining on the Schedule and recommended the deletion of the products.

B. Braun Australia Pty Ltd is to advise stoma associations, ostomates, stomal therapy nurses and the Australian Council of Stoma Associations of the deletion. A period of approximately 6 months from the date of the recommendation (12 November 2024) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.

### Context for Recommendation

The Panel secretariat, in accordance with the SAS Application and Assessment Guidelines, usually processes product deletions requested by the sponsor. This includes consideration of whether appropriate alternative products remain available on the SAS Schedule.

### Applicant's Comment

The applicant noted the recommendation.

### Addendum

To ensure there is no disruption in supply to current users, B.Braun has requested to postpone the deletion of this listing until the replacement product, B. Braun Australia Pty Ltd Flexima® High Flow (BB#07), is recommended for listing by the Panel. The Panel secretariat will postpone the deletion pending a decision on listing of the replacement product.