



# Stoma Product Assessment Panel

## Public Summary Documents

### Coloplast – 24 October 2023

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## Coloplast Conseal – CT#01OCTOBER2023

### Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast, sought the deletion of the entire product range of the current listing of Coloplast Conseal (SAS Code 3641P) in subgroup 8(a) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued. The product, with 4 variants, is currently listed at a unit price of \$4.434, with a pack size of 10 and a maximum monthly quantity of 30 units.

### Substitute products

The sponsor did not nominate a comparator product.

### Variants to be deleted

Company Code	Description
1435	soft foam plug which is inserted into the stoma, blocks faeces and controls noise, one piece, cut to fit, 20-35 mm, 35mm plug length,
1445	soft foam plug which is inserted into the stoma, blocks faeces and controls noise, one piece, cut to fit, 20-35 mm, 45mm plug length,
1485	soft foam plug which is inserted into the stoma, blocks faeces and controls noise, one piece, cut to fit, 35-45 mm, 35mm plug length,
1495	soft foam plug which is inserted into the stoma, blocks faeces and controls noise, one piece, cut to fit, 35-45 mm, 45mm plug length,

### Background

This product was first listed on the SAS Schedule on 1 April 2011.

### Clinical Place for the Product

Not applicable.

### Financial Analysis

There are no substitute products available in subgroup 8(a) of the SAS Schedule at the same cost and maximum monthly quantity. It is expected the deletion will have a budgetary impact with an estimated save for the SAS which will be confirmed by the Department of Finance.

### Panel Recommendation

The Stoma Product Assessment Panel (the Panel) recommended the deletion of the entire product range of Coloplast Conseal (SAS Code 3641P) listed in subgroup 8(a) of the SAS Schedule. The Panel noted there is no equivalent product remaining on the Schedule.

Coloplast 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 (24 October 2023) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels. As there are no substitute products listed on the SAS Schedule, the Panel secretariat will also inform stoma associations and the Australian Association of Stomal Therapy Nurses of the product deletion prior to the SAS Schedule update.



### Context for Recommendation

The Panel's discussion of deletion requests includes consideration of whether appropriate alternative products remain available on the SAS Schedule.

### Applicant's Comment

The applicant noted the recommendation.



## Coloplast New SenSura Mio – CT#02OCTOBER2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of 2 additional variants of Coloplast New SenSura Mio in subgroup 2(a) of the Stoma Appliance Scheme (SAS) Schedule. The 2 additional variants were proposed for listing at a unit price of \$4.879, including a price premium price of \$0.205, with a pack size of 30 and a maximum monthly quantity of 90 units.

### Comparator

The applicant nominated Coloplast New SenSura Mio (SAS Code 3998K) as the comparator. The comparator product (11 variants) is currently listed in subgroup 2(a) of the SAS Schedule at a unit price of \$4.879, including a price premium of \$0.205, with a pack size of 30 and a maximum monthly quantity of 90 units.

### Background

This application was to add 2 variants to the existing product range of Coloplast New SenSura Mio (SAS Code 3998K). The product was first listed on the SAS Schedule on 1 October 2014.

### Clinical Place for the Product

The proposed product provides an alternative for users requiring a one-piece drainable pouch with a cut to fit hydrocolloid flat baseplate.

### Clinical Analysis

The Panel noted that this application was to add 2 variants to an existing product range to include 2 additional size pouches, 520ml and 790ml. The Panel noted that the additional sizes were a useful addition to the product range.

### Economic Analysis

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

### Financial Analysis

Listing of additional variants of this product is unlikely to have a budgetary impact for the SAS as it will be listed at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost to the SAS.

### Panel Recommendation

The Panel recommended that 2 new variants of the Coloplast New SenSura Mio be listed in subgroup 2(a) of the SAS Schedule, at the unit price of \$4.879, including a price premium of \$0.205, with a pack size of 30 and a maximum monthly quantity of 90 units. The product codes for the new variants are to be added under the existing SAS code 3998K.



### 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. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## Coloplast New SenSura Mio – CT#03OCTOBER2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of 2 additional variants to the Coloplast New SenSura Mio in subgroup 1(b) of the Stoma Appliance Scheme (SAS) Schedule. The 2 additional variants were proposed for listing at a unit price of \$3.009, including a price premium of \$0.274, with a pack size of 30 and a maximum monthly quantity of 90 units.

### Comparator

The applicant nominated Coloplast New SenSura Mio (SAS Code 3991C) as the comparator. The product (10 variants) is currently listed in subgroup 1(b) of the SAS Schedule at the unit price of \$3.009, including a price premium of \$0.274 with a pack size of 30 and a maximum monthly quantity of 90 units.

### Background

This application was to add 2 variants to the existing product range of Coloplast New SenSura Mio (SAS Code 3991C). The product was first listed on the SAS Schedule on 1 October 2014.

### Clinical Place for the Product

The proposed product is for users requiring a one piece closed pouch with a cut to fit hydrocolloid flat baseplate.

### Clinical Analysis

The Panel noted that this application was to add 2 variants to an existing product range to include 2 additional size pouches, 580ml and 820ml. The Panel noted that the additional sizes were a valuable addition to the product range.

### Economic Analysis

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

### Financial Analysis

Listing of additional variants of this product is unlikely to have a budgetary impact for the SAS as it will be listed at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost to the SAS.

### Panel Recommendation

The Panel recommended 2 new variants of the Coloplast New SenSura Mio be listed in subgroup 1(b) of the SAS Schedule, at the unit price of \$3.009, including a price premium of \$0.274, with a pack size of 30 and a maximum monthly quantity of 90 units. The product codes for the new variants are to be added under the existing SAS code 3991C.



### 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. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## Coloplast Self-cath – CT#04OCTOBER2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of 3 additional variants of Coloplast Self-cath in subgroup 8(c) of the Stoma Appliance Scheme (SAS) Schedule. The 3 additional variants were proposed for listing at a unit price of \$1.034, with a pack size of 30 and a maximum monthly quantity of 120 units.

### Comparator

The applicant nominated Coloplast Self-cath (SAS Code 9867H) as the comparator. The product (5 variants) is currently listed in subgroup 8(c) of the SAS Schedule at the unit price of \$1.034, with a pack size of 30 and a maximum monthly quantity of 120 units.

### Background

This application was to add 3 existing variants to the existing product range of Coloplast Self-cath (SAS Code 9867H). The product was first listed on the SAS on 1 April 2011.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a soft nelaton catheter for drainage opposed to the firm catheter listed in the current product range.

### Clinical Analysis

The Panel noted that this application was to add 3 variants to an existing product range to include a soft catheter opposed to the firm catheter already available in the current product range.

The Panel noted that these catheters are used for self-catheterisation and that catheter products for self-catheterisation have limited utility in ostomates.

### Economic Analysis

The Panel noted that if the listing of additional variants of this product was recommended in the future, it would be recommended at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost to the SAS.

### Financial Analysis

Should listing of additional variants of this product be recommended in the future, it is unlikely to have a budgetary impact for the SAS. The variants would be listed at the same price and same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost on the SAS Schedule.

### Panel Recommendation

The Panel considered the appropriateness of catheter products on the SAS Schedule and noted the limited utility of catheter products in ostomates for the purpose of the SAS. The Panel agreed to defer the consideration of the application to list 3 additional variants of the Coloplast Self-cath in subgroup 8(c) pending the conclusion of the Schedule Review. This





Review will consider whether catheter products should continue to be listed on the SAS Schedule.

#### 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.

#### Applicant's Comment

Coloplast is disappointed by SPAP's decision.

The Stoma Appliance Scheme Schedule Review, Terms of Reference does not stipulate that while the Schedule review is being conducted that SPAP withhold decision making until the review is concluded.

It is unclear why SPAP would recommend listing of variants of other products but not Self-Cath (soft) catheter, when the soft catheter addresses a gap in the current range of catheters, the committee acknowledges that it is unlikely to have a budgetary impact for the SAS and the completion of the review is not expected until the end of 2024.



## Coloplast Adhesive Sleeve – CT#05OCTOBER2023

### Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast, sought the deletion of the entire product range of the current listing of Coloplast Adhesive Sleeve (SAS Code 3895B) in subgroup 8(b) of the Stoma Appliance Scheme (SAS) Schedule, as the product is being discontinued. The product, with one variant, is currently listed at a unit price of \$1.309 with a pack size of 50 and a maximum monthly quantity of 50 units.

### Substitute products

Sensura Mio 1-piece Irrigation Sleeve (Company Code 117501), recommended by the Stoma Product Assessment Panel (the Panel) at the October 2023 meeting (CT#06OCTOBER2023), subject to agreement by Government.

### Variant to be deleted

Company Code	Description
1003	one-piece adhesive irrigation sleeve, clear

### Background

This product was first listed on the SAS Schedule on 1 April 2011.

### Clinical Place for the Product

Not applicable.

### Financial Analysis

Substitute products are not currently listed in subgroup 8(b) of the SAS Schedule at the same cost and maximum monthly quantity. A substitute product has been recommended for listing by the Panel and is expected to be listed in parallel with the deletion of this product, subject to agreement by Government. It is unlikely that there would be any budgetary impact for the SAS as a consequence of deleting this product.

### Panel Recommendation

The Panel noted that an equivalent product will be added to the Schedule (subject to Government agreement) and recommended the deletion of the entire product range (one variant) of Coloplast Adhesive Sleeve (SAS Code 3895B) listed in subgroup 8(b) of the SAS Schedule.

Coloplast 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 (24 October 2023) 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's discussion of deletion requests includes consideration of whether appropriate alternative products remain available on the SAS Schedule. Suggested alternative products are noted by the Panel but not referenced in the SAS Schedule.

### Applicant's Comment

The applicant noted the recommendation.



## Coloplast SenSura Mio 1-piece Irrigation Sleeve – CT#06OCTOBER2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of the Coloplast Sensura Mio 1-piece Irrigation Sleeve in subgroup 8(b) of the Stoma Appliance Scheme (SAS) Schedule. The product (one variant) was proposed for listing at a unit price of \$1.309, with a pack size of 50 and a maximum monthly quantity of 50 units.

### Comparator

The applicant nominated Coloplast Adhesive Sleeve (SAS Code 3895B) as the comparator. The comparator product (one variant) is proposed for deletion, but is currently listed in subgroup 8(c) of the SAS Schedule at the unit price of \$1.309, with a pack size of 50 and a maximum monthly quantity of 50 units.

### Background

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

### Clinical Place for the Product

The proposed product is a replacement for ostomates previously using the Coloplast Adhesive Sleeve listed under SAS Code 3895B, company code 1003 on the SAS Schedule.

### Clinical Analysis

The Panel noted that this product is to replace the existing listing due to an upgrade in technology of an improved adhesive. The Panel noted that ostomates should not need to use this product more than once a day, and that a maximum monthly quantity of 30 should be sufficient rather than 50. Noting the administrative challenges that a maximum monthly quantity of 30 would present, the Panel will consider the maximum quantity for this product in the context of the SAS Schedule Review.

### Economic 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 will result in the same monthly cost to the SAS.

### Financial Analysis

Listing of this product is unlikely to have a budgetary impact for the SAS as it will be listed at the same price and the same maximum monthly quantity as currently listed products in the same subgroup, resulting in the same monthly cost to the SAS.



### Panel Recommendation

The Panel recommended that the Coloplast Sensura Mio 1-piece Irrigation Sleeve be listed in subgroup 8(b) of the SAS Schedule with one variant, at the unit price of \$1.309, with a maximum monthly quantity of 50 units.

### 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. The Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

### Applicant's Comment

The applicant noted the recommendation.



## Coloplast Conveen Basic Bag – CT#07OCTOBER2023

### Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of the Coloplast Conveen Basic Bag as an addition to an existing product range in subgroup 9(i) of the Stoma Appliance Scheme (SAS) Schedule. The additional one variant was proposed for listing at a unit price of \$2.190, with a pack size of 10. The applicant did not propose a maximum quantity.

### Comparator

The applicant nominated Coloplast S3 Extended Term (SAS Code 3674J) as the comparator. The product (one variant) is currently listed in subgroup 9(i) of the SAS Schedule at the unit price of \$2.190, with a pack size of one and a maximum monthly quantity of 5 units.

### Background

This application was to add one variant to the existing product range of Coloplast S3 Extended Term (SAS Code 3674J). The product was first listed on the SAS Schedule on 1 April 2011.

### Clinical Place for the Product

The proposed product would provide an alternative for users requiring a bedside drainage bag with a T-tap free flow option.

### Clinical Analysis

The Panel noted that this application was to add one variant to an existing product range to include a bedside drainage bag with a T-tap free flow option.

### Economic Analysis

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

### Financial Analysis

Listing of an additional variant of this product is unlikely to have a budgetary impact for the SAS as it will be listed at the same price and the same maximum quantity as currently listed products in the same subgroup, resulting result in the same monthly cost to the SAS.

### Panel Recommendation

The Panel recommended that the Coloplast Conveen Basic Bag be listed as an additional variant of an existing product range in subgroup 9(i) of the SAS Schedule, at the unit price of \$2.190, with a pack size of 10 and a maximum annual quantity of 60 units. The product code for the new variant is to be added under the existing SAS code 3674J.

### 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. The



**Australian Government**

**Department of Health and Aged Care**

Panel is an advisory committee and as such its recommendations are non-binding on Government. All Panel recommendations are subject to Government approval.

#### **Applicant's Comment**

The applicant noted the recommendation.