Australian Government
Department of Health and Aged Care

Stoma Product Assessment Panel Public Summary Documents Coloplast Pty Ltd – 2 May 2023

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Coloplast Protective Sheet Dispenser – CT#01MAY2023

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the current listing of Coloplast Protective Sheet Dispenser (SAS Code 3509Q) in subgroup 9(a) of the Stoma Appliance Scheme (SAS) Schedule, due to the inability to source materials to manufacture the product. The product is currently listed at a unit price of $47.142 with a maximum monthly quantity of one unit.

Substitute product

Coloplast Brava Protective Sheet (SAS Code: 3944N)

Variant to be deleted

Product Code	Description
3250	soft, thin elastic material that absorbs moisture, in a dispenser 2x10cm

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 currently listed in subgroup 9(a) 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.

Recommendation

As this was an administrative change, this application was considered by the Panel secretariat in line with the SAS *Application and Assessment Guidelines*. The Panel secretariat, noting equivalent products remained on the Schedule, recommended the deletion of the one variant for Coloplast Protective Sheet Dispenser (SAS Code 3509Q) in subgroup 9(a) of the SAS Schedule. The Panel noted the secretariat's recommendation at the May 2023 meeting.

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 (2 May 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 secretariat, in accordance with the SAS *Application and Assessment Guidelines*, usually processes deletions to products. This includes consideration of whether appropriate alternative products remain available on the SAS Schedule. Suggested alternative products are noted by the secretariat but not referenced in the SAS Schedule.

Applicant's Comment

The applicant noted the recommendation.

Coloplast SenSura Mio – 1 Piece Soft Convexity Closed – CT#02MAY2023

Proposed Variation on the Stoma Appliance Scheme

The applicant, Coloplast, sought a change in the product name for 3 variants and in the description to one variant of the current listing of the Coloplast SenSura Mio – 1 Piece Soft Convexity Closed (SAS Code 80043T) in subgroup 3(b) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 6 variants, is currently listed at a unit price of $6.373, with a maximum monthly quantity of 30 units.

Variation requested

The applicant requested the product name for 3 variants change from Coloplast SenSura Mio – 1 Piece Soft Convexity Closed to Coloplast SenSura Mio – 1 Piece Soft Convexity Urostomy so that all 6 variants have the same name.

Product Code	Product Name
13679 13678 13680	Name changing from: Coloplast Coloplast SenSura Mio - 1 Piece Soft Convexity Closed to Coloplast SenSura Mio - 1 Piece Soft Convexity Urostomy

The applicant also requested changes to the description of the existing listing for SAS Code 80043T, Company Code 13679.

Product Code	Description
13679	Description changing from ‘opaque with fabric cover on both sides’ to ‘transparent with fabric backing’

Background

This product was first listed on the SAS Schedule on 1 October 2022.

Financial Analysis

Changing the name of 3 variants of the product to Coloplast SenSura Mio – 1 Piece Soft Convexity Urostomy will provide consistency for all products listed under SAS Code 80043T. The change in the description to product with Company Code: 13679 will more accurately describe the product. As there is no change to the price or maximum monthly quantity, this variation is unlikely to have a budgetary impact for the SAS.

Recommendation

As this was only an administrative change, this application was considered by the Panel secretariat in line with the SAS *Application and Assessment Guidelines*. The Panel secretariat recommended the change in the product name for 3 variants of Coloplast SenSura Mio – 1 Piece Soft Convexity Urostomy and description of one variant of the current product (SAS Code 80043T) in subgroup 3(b) of the SAS Schedule at the unit price of $6.373, with a maximum monthly quantity of 30 units. The Panel noted the secretariat's recommendation at the May 2023 meeting.

Context for Recommendation

The Panel secretariat, in accordance with the SAS *Application and Assessment Guidelines*, can process variations to products where there is no change to classification, pricing, maximum quantity or composition. All recommendations are subject to Government approval.

Applicant's Comment

The applicant noted the recommendation.

Peristeen Plus – CT#03MAY2023

Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of Peristeen Plus with 3 variants in subgroup 8(b) of the Stoma Appliance Scheme (SAS) Schedule, for use in adults. Peristeen Plus was added to the SAS Schedule on 1 April 2023 for use in children aged 3 to 17 years.

Comparator

The applicant nominated Standard Medical Management (SMM) as the comparator.

Background

This was the Stoma Product Assessment Panel's (the Panel) third consideration of this product, noting the recommendation to list from the October 2022 Panel meeting was restricted for use in children aged 3 to 17 years.

Clinical Place for the Product

The proposed listing would provide a water-based transanal irrigation system product for adults with anorectal malformations or an imperforate anus. Peristeen Plus is indicated for patients who have continued faecal incontinence where SMM therapies of oral laxatives and retrograde enemas have failed. The Panel noted input from consumers and clinicians regarding the use of Peristeen Plus in adults with ARM.

Clinical Analysis

The Panel noted the clinical analysis used in both previous submissions in April 2022 and October 2022 for Peristeen Plus and agreed on the clinical efficacy of the product in children. However, the Panel did not consider this evidence could be compared directly with adult studies as it is uncertain if the effectiveness would be equivalent in adults compared to children. The applicability of the key study presented to the target patient group is also uncertain as the study cited patients with spinal cord injury, with 76% in a wheelchair and 18% with faecal incontinence, rather than those with anorectal malformation or imperforate anus.

Economic Analysis

The Panel acknowledged that the additional information provided by the applicant to support use in adults was limited due to scarcity of data available and sample sizes for this patient cohort. The utility gain was applied to all cycles of the model presented which caused uncertainty in the cost effectiveness. The Panel noted there were limitations in the financial model and limitations in utility data and questioned the ICER value presented.

Financial Analysis

Financial estimates in listing of this product would be sensitive to the discontinuation rate, frequency of use, patient uptake rate and incident population. Current availability of data

precludes accurate estimates of the budgetary impact for the SAS should the product be recommended for listing.

Panel Recommendation

The Panel rejected the application for Peristeen Plus for use in adults to be listed in subgroup 8(b) of the SAS Schedule at this time.

The Panel noted the limitations in available clinical data and evidence in adults in the target patient group and recommended that any reapplication for listing of the product for use in adults should be informed by sufficient utilisation data and analysis from the recently approved listing of Peristeen Plus in children. The Panel indicated that they would welcome a reapplication from the sponsor once more data are available in relation to use of Peristeen Plus specifically in adults with ARM; and/or utilisation data in children that could inform expectations regarding use in the adult population.

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

The strong clinical need for use of Peristeen Plus in adult ARM patients is not acknowledged in this Public Summary Document.

Coloplast's request for a meeting with the Chair of the Stoma Product Assessment Panel to seek guidance on what would be acceptable evidence to support this application was rejected.

Coloplast is keen to make Peristeen available to adults with ARM, and having made three applications to SPAP, there is no collaboration from the Department of Health and Aged Care or Stoma Product Assessment Panel to provide guidance to the Sponsor on the approach.

Coloplast is disappointed with this decision as adults with ARM are suffering.