

Stoma Product Assessment Panel Public Summary Documents Coloplast Pty Ltd – 18 October 2022

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Department of Health and Aged Care

Peristeen Plus – CT#010CT2022

Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought listing of the Peristeen Plus in subgroup 8(b) of the Stoma Appliance Scheme (SAS) Schedule. The product was proposed for listing at an annual price and maximum quantity as indicated in the April 2022 submission.

Comparator

The applicant nominated standard medical management (SMM) as the comparator. The Panel considered this was appropriate and noted there is no comparable product currently available on the SAS.

Background

This was the Stoma Product Assessment Panel's (the Panel) second consideration of this product, with a decision deferred from the April 2022 Panel meeting¹.

Clinical Place for the Product

The proposed listing provides a product for users aged 3 years or over 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 (claimed in the submission to be approximately 40% of patients).

Clinical Analysis

The Panel noted the clinical analysis used in the previous submission in April 2022 for Peristeen Plus and agreed on the clinical efficacy of the product with the clinical evidence supporting use in children over 3 years. The Panel did not consider that the evidence provided supported use in adults.

Economic Analysis

Following the deferred application in April 2022 and the Panel's request for additional information, the Panel acknowledged that although additional information was provided by the applicant there were limitations in the financial model due to the available sample size. The Panel noted the model provided by Coloplast had limitations in utility data and questioned the ICER value presented.

Financial Analysis

The Panel agreed if the product was listed, the availability would be restricted to a specific patient group of children aged 3 to 17 years as supported by the clinical evidence provided in the application. The Panel requested the applicant provide a revised uptake estimates and financial information for this specific age group.

¹ <u>SPAP public summary document – April 2022 – Coloplast Peristeen Plus | Australian Government</u> <u>Department of Health and Aged Care</u>



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Panel Recommendation

The Panel provisionally recommended the Peristeen Plus application subject to further information from Coloplast. The Panel discussed that if the product is listed on the Scheme, it will incur a R4 restriction requiring referral from a paediatric surgeon and the following specific restrictions:

- restricted for patients aged 3 to 17 years (adults to be excluded for access to the product on the SAS Schedule)
- referral from a paediatric surgeon renewed annually on a specific Departmental form for this product
- compulsory education by a specialist continence clinician on usage prior to supply.

The Panel requested that Coloplast provide:

- uptake estimates and financial information for the age group recommended
- clarity the catheter pack quantities.

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 pleased that Peristeen Plus will be made available through the SAS to children with anorectal malformations or an imperforate anus.



Department of Health and Aged Care

Coloplast Easiflex Alterna – CT#02OCT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the entire product range from the current listing of Coloplast Easiflex Alterna (SAS Codes 9935X and 9956B) in subgroup 5(b) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to availability of new technology. The product, including 8 variants, is currently listed at a unit price of \$1.564 with a maximum monthly quantity of 90 units.

Substitute products

Coloplast SenSura Mio (SAS Code: 80015H) (see discussion under Financial Analysis below)

Variants to be deleted

Product Code	Description
14314	Coloplast Easiflex Alterna
14316	Coloplast Easiflex Alterna
14317	Coloplast Easiflex Alterna
14319	Coloplast Easiflex Alterna
14327	Coloplast Easiflex Alterna
14331	Coloplast Easiflex Alterna
14332	Coloplast Easiflex Alterna
14355	Coloplast Easiflex Alterna

Background

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

Clinical Place for the Product

Not applicable.

Financial Analysis

The Panel noted that the alternative product nominated by the applicant is listed with a unit price of \$1.769 including a price premium of \$0.205; but also noted that other substitute products are currently listed in subgroup 5(b) of the SAS Schedule at the same cost and maximum monthly quantity as the proposed deleted products. As products are available at the same cost, it is unlikely that there would be any budgetary impact for the SAS as a consequence of deleting this product.

Panel Recommendation

The Panel, noting new technology is available and equivalent products remain on the Schedule, recommended the deletion of the entire product range of Coloplast Easiflex Alterna (SAS Code 9935X and 9956B) listed in subgroup 5(b) 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



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6 months from the date of the recommendation (18 October 2022) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.

The Panel encourages applicants seeking deletions to consider the appropriateness of nominating a substitute product at a higher price when products at the benchmark price are available.

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



Department of Health and Aged Care

Coloplast Easiflex Alterna – CT#03OCT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of 9 variants from the current listing of Coloplast Easiflex Alterna (SAS Code 9938C) in subgroup 6(b) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to availability of new technology. The product, including 13 variants, is currently listed at a unit price of \$3.504 with a maximum monthly quantity of 60 units.

Substitute products

Coloplast SenSura Flex EasiClose (SAS Code: 9790G)

Variants to be deleted

Product Code	Description
14344	Coloplast Easiflex Alterna
14346	Coloplast Easiflex Alterna
14347	Coloplast Easiflex Alterna
14349	Coloplast Easiflex Alterna
14357	Coloplast Easiflex Alterna
14361	Coloplast Easiflex Alterna
14362	Coloplast Easiflex Alterna
14378	Coloplast Easiflex Alterna
14379	Coloplast Easiflex Alterna

Background

This product was first listed on the SAS Schedule on 1 April 2014.

Clinical Place for the Product

Not applicable.

Financial Analysis

Substitute products are currently listed in subgroup 6(b) of the SAS Schedule at the same cost and maximum monthly quantity. It is unlikely that there would be any budgetary impact for the SAS as a consequence of deleting 9 variants of 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of 9 variants of Coloplast Easiflex Alterna (SAS Code 9938C) listed in subgroup 6(b) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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



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6 months from the date of the recommendation (18 October 2022) 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

Department of Health and Aged Care

Coloplast SenSura Mio – CT#05OCT2022

Proposed Variation on the Stoma Appliance Scheme

The applicant, Coloplast, sought the addition of one variant to the current listing of the Coloplast SenSura Mio (SAS Code 80015H) in subgroup 5(b) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 10 variants, is currently listed at a unit price of \$1.769 including a price premium of \$0.205, with a maximum monthly quantity of 90 units.

Variants to be added

The applicant requested the following variant be added to the existing listing for SAS Code 80015H.

Product Code	Description
18386	Protected single carbon filter, transparent with fabric cover on both sides including viewing window, 430ml, extra large, no belt loops, adhesive coupling, low headspace.

Background

This product was first listed on the SAS Schedule on 1 May 2015.

Financial Analysis

Listing this variant will provide ostomates with an additional size to choose from and will be listed at the same price and same maximum monthly quantity as the current product range. Listing the variant to the current product range 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 addition of one variant to the current product range for Coloplast SenSura Mio (SAS Code 80015H) listed in subgroup 5(b) of the SAS Schedule at the unit price of \$1.769, including a price premium of \$0.205, with a maximum monthly quantity of 90 units. The product code for the new variant to be added under SAS Code 80015H is 18386. The Panel noted the secretariat's recommendation at the October 2022 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

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Coloplast SenSura Mio – CT#06OCT2022

Proposed Variation on the Stoma Appliance Scheme

The applicant, Coloplast, sought the addition of one variant to the current listing of the Coloplast SenSura Mio (SAS Code 80010C) in subgroup 4(d) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 9 variants, is currently listed at a unit price of \$5.232 with a maximum monthly quantity of 30 units.

Variants to be added

The applicant requested the following variant be added to the existing listing for SAS Code 80010C.

Product Code	Description
18390	Hydrocolloid, 1.3mm, oval, hydrocolloid self-adhesive, standard, cut-to-fit, from 10mm to 88mm, adhesive coupling, floating flange, no belt loops, 90mm, release tabs.

Background

This product was first listed on the SAS Schedule on 1 May 2015.

Financial Analysis

Listing this variant will provide ostomates with an additional size option. The additional variant will be listed at the same price and same maximum monthly quantity as the current product range. Listing the variant to the current product range 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 *Application and Assessment Guidelines*. The Panel secretariat recommended the addition of one variant to the current product range for Coloplast SenSura Mio (SAS Code 80010C) listed in subgroup 4(d) of the SAS Schedule at the unit price of \$5.232, with a maximum monthly quantity of 30 units. The product code for the new variant to be added under SAS Code 80010C is 18390. The Panel noted the secretariat's recommendation at the October 2022 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

Department of Health and Aged Care

Coloplast SenSura Mio – CT#070CT2022

Proposed Variation on the Stoma Appliance Scheme

The applicant, Coloplast, sought the addition of one variant to the current listing of the Coloplast SenSura Mio (SAS Code 80012E) in subgroup 6(b) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 9 variants, is currently listed at a unit price of \$3.709, including a price premium of \$0.205, with a maximum monthly quantity of 30 units.

Variants to be added

The applicant requested the following variant be added to the existing listing for SAS Code 80012E.

Product Code	Description
18388	Protected single carbon filter, transparent with fabric cover on both sides including viewing window, 430m, extra large, no belt loops, adhesive coupling, integrated closure, low headspace.

Background

This product was first listed on the SAS Schedule on 1 May 2015.

Financial Analysis

Listing this variant will provide ostomates with an additional size option. The additional variant will be listed at the same price and same maximum monthly quantity as the current product range. Listing the variant to the current product range 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 *Application and Assessment Guidelines*. The Panel secretariat recommended the addition of one variant to the current product range for Coloplast SenSura Mio (SAS Code 80012E) listed in subgroup 6(b) of the SAS Schedule at the unit price of \$3.709, including a price premium of \$0.205, and with a maximum monthly quantity of 30 units. The product code for the new variant to be added under SAS Code 80012E is 18388. The Panel noted the secretariat's recommendation at the October 2022 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

Department of Health and Aged Care

Coloplast Easiflex Alterna – CT#08OCT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of 5 variants from the current listing of Coloplast Easiflex Alterna (SAS Code 9957C) in subgroup 4(d) of the Stoma Appliance Scheme (SAS) Schedule, as they are being discontinued due to availability of new technology. The product, including 7 variants, is currently listed at a unit price of \$5.005 including a pack premium per unit of \$0.227, with a maximum monthly quantity of 30 units.

Substitute products

Coloplast SenSura Mio (SAS Code: 80010C)

Variants to be deleted

Product Code	Description
14301	Coloplast Easiflex Alterna
14302	Coloplast Easiflex Alterna
14303	Coloplast Easiflex Alterna
14387	Coloplast Easiflex Alterna
14388	Coloplast Easiflex Alterna

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 4(d) of the SAS Schedule at the same cost and maximum monthly quantity. It is unlikely that there would be any budgetary impact for the SAS as a consequence of deleting 5 variants of 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of 5 variants from the product range (7 variants) for Coloplast Easiflex Alterna (SAS Code 9957C) listed in subgroup 4(d) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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 (18 October 2022) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.



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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



Department of Health and Aged Care

Coloplast Easiflex Alterna Extra – CT#09OCT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the entire product range from the current listing of Coloplast Easiflex Alterna Extra (SAS Code 9937B) in subgroup 4(d) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to availability of new technology. The product, including 3 variants, is currently listed at a unit price of \$5.232 with a maximum monthly quantity of 20 units.

Substitute products

Coloplast SenSura Mio (SAS Code: 80010C)

Variants to be deleted

Product Code	Description
14304	Coloplast Easiflex Alterna Extra
14305	Coloplast Easiflex Alterna Extra
14306	Coloplast Easiflex Alterna Extra

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 4(d) of the SAS Schedule at the same cost and maximum monthly quantity. It is 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of the entire product range (3 variants) for Coloplast Easiflex Alterna Extra (SAS Code 9937B) listed in subgroup 4(d) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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 (18 October 2022) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.



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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



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Coloplast Easiflex Alterna – CT#100CT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the entire product range from the current listing of Coloplast Easiflex Alterna (SAS Code 9936Y) in subgroup 4(d) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to availability of new technology. The product, including a single variant, is currently listed at a unit price of \$4.790 with a maximum monthly quantity of 30 units.

Substitute products

Coloplast SenSura Flex (SAS Code: 9789F)

Variants to be deleted

Product Code	Description
14309	Coloplast Easiflex Alterna

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 4(d) of the SAS Schedule at the same cost and maximum monthly quantity. It is 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of the entire product range (one variant) for Coloplast Easiflex Alterna (SAS Code 9936Y) listed in subgroup 4(d) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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 (18 October 2022) 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



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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



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Coloplast Easiflex Alterna - CT#110CT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the entire product range from the current listing of Coloplast Easiflex Alterna (SAS Code 9925J) in subgroup 4(f) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to availability of new technology. The product, including 3 variants, is currently listed at a unit price of \$6.930 with a maximum monthly quantity of 20 units.

Substitute products

Coloplast SenSura Flex (SAS Code: 9789F)

Variants to be deleted

Product Code	Description
14401	Coloplast Easiflex Alterna
14403	Coloplast Easiflex Alterna
14406	Coloplast Easiflex Alterna

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 4(f) of the SAS Schedule at the same cost and maximum monthly quantity. It is 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of the entire product range (3 variants) for Coloplast Easiflex Alterna (SAS Code 9925J) listed in subgroup 4(f) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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 (18 October 2022) should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.



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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



Department of Health and Aged Care

Coloplast Easiflex Alterna – CT#12OCT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the entire product range from the current listing of Coloplast Easiflex Alterna (SAS Code 9832L) in subgroup 4(f) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to availability of new technology. The product, including a single variant, is currently listed at a unit price of \$6.930 with a maximum monthly quantity of 20 units.

Substitute products

Coloplast SenSura Mio 2 Piece with Shallow Convexity (SAS Code: 80042R)

Variants to be deleted

Product Code	Description
14408	Coloplast Easiflex Alterna

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 4(f) of the SAS Schedule at the same cost and maximum monthly quantity. It is 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of the entire product range (one variant) for Coloplast Easiflex Alterna (SAS Code 9832L) listed in subgroup 4(f) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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 (18 October 2022) 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



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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



Department of Health and Aged Care

Coloplast Easiflex Alterna – CT#13OCT2022

Proposed Deletion on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the deletion of the entire product range from the current listing of Coloplast Easiflex Alterna (SAS Code 9819T) in subgroup 4(f) of the Stoma Appliance Scheme (SAS) Schedule, as it is being discontinued due to an upgrade available with new technology. The product, including 2 variants, is currently listed at a unit price of \$6.930 with a maximum monthly quantity of 20 units.

Substitute products

Coloplast SenSura Mio 2 Piece with Shallow Convexity (SAS Code: 80042R)

Variants to be deleted

Product Code	Description
14601	Coloplast Easiflex Alterna
14603	Coloplast Easiflex Alterna

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 4(f) of the SAS Schedule at the same cost and maximum monthly quantity. It is 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 an upgraded product and equivalent products remained on the Schedule, recommended the deletion of the entire product range (2 variants) for Coloplast Easiflex Alterna (SAS Code 9819T) listed in subgroup 4(f) of the SAS Schedule. The Panel noted the secretariat's recommendation at the October 2022 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 (18 October 2022) 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



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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