

PUBLIC SUMMARY DOCUMENT

Product: Esteem[®] + Flex Convex Closed

Applicant: ConvaTec (Australia) Pty Ltd

Date of SPAP Meeting: 11 April 2016

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, ConvaTec, sought listing of the Esteem[®] + Flex Convex Closed One-Piece pouch, in subgroup 1(c) of the Stoma Appliance Scheme (SAS) Schedule. The product including three variants, was proposed at the unit price of \$4.433 with a maximum monthly quantity of 60 units.

2. Comparator

The applicant nominated Coloplast Sensura Convex Closed one-piece pouch (SAS code 9851L) as the comparator. This product is currently listed in subgroup 1(c) of the SAS Schedule at a unit price of \$4.433, with a maximum monthly quantity of 60 units.

3. Background

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

4. Clinical Place for the Product

The proposed product provides as an alternative for users requiring a one-piece closed pouch with a convex baseplate.

5. SPAP Comment

Clinical Analysis

The Panel noted that the proposed product includes a protected carbon filter to minimise the risk of odour and ballooning. The Panel also noted that the applicant did not provide clinical data to verify any claim for superiority of this filter.

The Panel also noted that the proposed product has been marketed under the brand name Stomocur in Europe since 2009 and in that time no reportable adverse events have been reported.

The Panel agreed that the Esteem[®] + Flex Convex Closed is equivalent to products currently available at the benchmark price in subgroup 1(c), therefore listing on a cost minimisation basis was considered appropriate.

Economic Analysis

Not undertaken.

Financial Analysis

Listing of this product is recommended on a cost minimisation basis compared with the nominated comparator in subgroup 1(c) of the SAS Schedule. It is therefore unlikely that there would be any budgetary impact for the SAS as a consequence of listing this product under the conditions requested by the applicant.

6. SPAP Recommendation

The SPAP recommended that the Esteem[®] + Flex Convex Closed, including three variants, be listed in subgroup 1(c) of the SAS Schedule, at a unit price of \$4.433, with a maximum monthly quantity of 60 units.

7. Context for Decision

The SPAP helps decide whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. It considers submissions in this context. An SPAP decision not to recommend listing or changes to a listing does not represent a final SPAP view about the merits of a particular stoma product. A company can resubmit to the SPAP following a decision not to recommend listing or changes to a listing. The SPAP is an advisory committee and as such its recommendations are non-binding on Government. All SPAP recommendations are subject to Cabinet/Ministerial approval.

8. Applicant's Comment

ConvaTec (Australia) Pty Ltd agrees with the SPAP's recommendation contained in the Public Summary Document.