

## PUBLIC SUMMARY DOCUMENT

**Product:** Moderma Flex CeraPlus Soft Convex Drainable

**Applicant:** Hollister

**Date of SPAP Meeting:** 11 April 2016

### 1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Hollister, sought listing of the Moderma Flex CeraPlus Soft Convex Drainable pouch, in subgroup 2(b) of the Stoma Appliance Scheme (SAS) Schedule. The product, including 14 variants, was proposed at the unit price of \$6.578, inclusive of a price premium of \$0.205 over the benchmark unit price for subgroup 2(b) (\$6.373) with a maximum monthly quantity of 30 units.

The price premium requested was for the AF300 filter.

### 2. Comparator

The applicant nominated the Moderma Flex Drainable Convex One-Piece pouch (SAS code 5675Q) from its own range, which is currently listed in subgroup 2(b), as the comparator. This product is currently listed at the unit price of \$6.578, inclusive of a \$0.205 price premium with a maximum monthly quantity of 30 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 an alternative for users requiring a one-piece drainable pouch with convex baseplate. The product is a direct substitute for the comparator currently available in subgroup 2(b).

### 5. SPAP Comment

#### *Clinical Analysis*

The Panel noted that the proposed product contains the AF300 filter and is identical to the Moderma Flex Drainable Convex (SAS code 5675Q). The main difference between the two products is the addition of a viewing option and a ceramide infused skin barrier. Ceramide is a naturally occurring lipid in the skin. The Panel also noted that data on the use and safety of ceramide was provided, which it has considered in previous applications.

The Panel further noted that a clinical trial has commenced and that the data presented in the application claims that 85% of clinicians are satisfied with CeraPlus products and the Panel agreed that there appears to be no indication of adverse clinical issues with ceramide in barriers.

The SPAP has previously granted a price premium of \$0.205 for the AF300 filter in drainable bags, therefore no evidence was provided on the performance of the filter.

#### *Economic Analysis*

Not undertaken.

#### *Financial Analysis*

Listing of this product is recommended on a cost minimisation basis compared with the nominated comparator in subgroup 2(b) 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 Moderma Flex CeraPlus Soft Convex Drainable, including 14 variants, be listed in subgroup 2(b) of the SAS Schedule at a unit price of \$6.578, inclusive of a price premium of \$0.205 over the benchmark unit price for subgroup 2(b) (\$6.373), with a maximum monthly quantity of 30 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**

Hollister agrees with SPAP's recommendation.