

PUBLIC SUMMARY DOCUMENT

Product: New Image CeraPlus Flat cut-to fit (CTF) No Tape

Applicant: Hollister

Date of SPAP Meeting: 11 April 2016

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Hollister, sought listing of the New Image CeraPlus Flat CTF No Tape baseplate, in subgroup 4(b) of the Stoma Appliance Scheme (SAS) Schedule. The product including three variants, was proposed for listing at the unit price of \$4.742, with a maximum monthly quantity of 20 units.

2. Comparator

The applicant nominated the New Image CeraPlus with tape border (SAS code 80062T) from its own range, which is currently listed in subgroup 4(b), as the comparator. The comparator is listed at a unit price of \$4.742 with a maximum monthly quantity of 20 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 two-piece baseplate with mechanical coupling. The product is a direct substitute for the comparator currently available in subgroup 4(b).

5. SPAP Comment

Clinical Analysis

The Panel noted that the proposed product is a product extension to the existing New Image CeraPlus barrier range. The Panel also noted that the only difference is that the proposed product does not have a tape border and that there is no change to the actual component of the barrier.

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. The Panel agreed that there appears to be no indication of adverse clinical issues with ceramide in barriers.

Economic Analysis

Not undertaken.

Financial Analysis

Listing of this product is recommended on a cost minimisation basis compared with the nominated comparator in subgroup 4(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 New Image CeraPlus Flat CTF No Tape be listed in subgroup 4(b) of the SAS Schedule, at a unit price of \$4.742, with a maximum monthly quantity of 20 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 to SPAP's recommendation.