

PUBLIC SUMMARY DOCUMENT

Product: Aquaflush ACE Stoma Stopper

Applicant: New Medical

Date of SPAP Meeting: 11 April 2016

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, New Medical, sought listing of the Aquaflush ACE Stoma Stopper, in subgroup 8(a) of the Stoma Appliance Scheme (SAS) Schedule. The product including five variants, was proposed at the unit price of \$51.54 with a maximum monthly quantity of one unit.

2. Comparator

The applicant nominated AMSL Medicina Ace Stopper (SAS code 9854E), which is currently listed in subgroup 8(a), as the comparator. This product is currently listed at a unit price of \$51.54 with a maximum monthly quantity of one unit. This product requires Stomal Therapy Nurse (STN) or Health Care Professional (HCP) authorisation prior to being supplied.

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 stoma stopper.

5. SPAP Comment

Clinical Analysis

The Panel noted that the proposed product is utilised by patients to seal and keep stoma sites open and that the majority of patients are of school age.

The Panel also noted that the currently listed AMSL Medicina ACE Stopper is not available in Australia at the moment and there is urgent clinical need for a stoma stopper to be listed on the Schedule.

Economic Analysis

Not undertaken.

Financial Analysis

Listing of this product is recommended on a cost minimisation basis compared with the nominated comparator product in subgroup 8(a) 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 Aquaflush ACE Stoma Stopper be listed in subgroup 8(a) of the SAS Schedule, at a unit price of \$51.54, with a maximum monthly quantity of one unit. This product will also be classified with a R1 Restriction - requires Stomal Therapy Nurse (STN) or Health Care Professional (HCP) authorisation.

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

New Medical provided no comment on the SPAP recommendation.