Public summary document

Product: ConvaTec Natura Durahesive Skin Barrier **Applicant:** ConvaTec Australia Pty Ltd **Date of SPAP Meeting:** 26 April 2022

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, ConvaTec Australia Pty Ltd, sought listing of the ConvaTec Natura Durahesive Skin Barrier in subgroup 4(a) of the Stoma Appliance Scheme (SAS) Schedule. The product, with one variant, was proposed for listing at a unit price of \$4.141, with a maximum monthly quantity of 30 units.

2. Comparator

The applicant nominated (SAS Code 3777T) as the comparator. The product (3 variants) is currently listed in subgroup 4(a) of the SAS Schedule at the unit price of \$4.141, with a maximum monthly quantity of 30 units.

3. Background

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

4. Clinical Place for the Product

The proposed product is an alternative for users requiring a two-piece baseplate.

5. SPAP Comment

The applicant ConvaTec proposed that the existing SAS code (3777T) be used for the new application. The existing SAS code cannot be used and therefore a new SAS code will be allocated to this application.

6. Clinical Analysis

The Panel noted that the proposed product is a replacement for the comparator, Natura Durahesive Skin Barrier (SAS Code 3777T) and the sponsor ConvaTec stated that no further clinical evidence is warranted due to the new product being comparable to the predecessor.

7. Economic Analysis

The Panel noted that the proposed product is a replacement for the comparator, Natura Durahesive Skin Barrier (SAS Code 3777T) and the sponsor ConvaTec stated that no economic analysis is required due to the new product being comparable to the predecessor.

8. Financial Analysis

Listing of this product is unlikely to have a budgetary impact for the SAS.

9. SPAP Recommendation

The Panel deferred the application. The Panel sought further information from the supplier to clarify the intent of the submission.

10. 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.

11. Addendum

The applicant, ConvaTec, provided additional information for this application following the meeting and the Panel subsequently recommended that the ConvaTec Natura Durahesive Skin Barrier be listed in subgroup 4(a) of the SAS Schedule with one variant, at the unit price of \$4.141, with a maximum monthly quantity of 30 units.

12. Applicant's comment

The applicant noted the SPAP recommendation.