

Public summary document

Product: Omnigon G-3 AMPatch Stoma Cover

Applicant: Omnigon Pty Ltd

Date of SPAP Meeting: 26 April 2022

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Omnigon Pty Ltd, sought listing of the Omnigon AMPatch Stoma Cover in subgroup 9(m) of the Stoma Appliance Scheme (SAS) Schedule. The product (one variant) was proposed for listing at a unit price of \$2.793, with a maximum monthly quantity of 60 units.

2. Comparator

The applicant did not nominate a comparator product.

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 for users requiring a stoma cover for continent intestinal reservoir or continent urostomies to absorb fluid due to leakage from the created nipple valve.

5. Clinical Analysis

No clinical evidence was provided in the submission.

6. Economic Analysis

Insufficient evidence was provided in the submission.

7. Financial Analysis

Not applicable.

8. SPAP Recommendation

The Panel rejected the proposed listing of the G-3 Omnigon AMPatch Stoma Cover, including one variant, due to insufficient clinical, safety and economic information to support the applicant's claims.

While the Panel acknowledged the potential role for the G-3 AMPatch Stoma Covers in selected patients, the Panel required additional information to support the clinical place against usual care. The Panel would welcome a resubmission of the application with the additional requested information.

9. 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.

10. Applicant's Comment

The applicant noted the SPAP recommendation.