PUBLIC SUMMARY DOCUMENT

Product: SenSura Mio One-Piece Deep Convexity Drainable
Applicant: Coloplast Pty Ltd
Date of SPAP Meeting: 11 April 2016

1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought continued listing of the SenSura Mio One-Piece Deep Convexity Drainable pouch, in subgroup 2(b) of the Stoma Appliance Scheme (SAS) Schedule. The applicant proposed a unit price of $7.326, inclusive of a price premium of $0.953 over the benchmark unit price for subgroup 2(b) ($6.373).

2. Comparator

The applicant nominated the SenSura One-Piece Convex Drainable pouch (SAS code 9850K) 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 $6.373, with a maximum monthly quantity of 30 units.

3. Background

The SenSura Mio One-Piece Deep Convexity Drainable, has been listed in subgroup 2(b) of the SAS Schedule (SAS code 80040P), with 11 variants and a maximum monthly quantity of 30 units, at a unit price of $6.373 since 1 April 2016.

4. Clinical Place for the Product

The product remains suitable for users requiring a one-piece drainable pouch with deep convex baseplate.

5. SPAP Comment

Clinical Analysis

The Panel noted that the product was recommended at the benchmark price in August 2015 based on the evidence that was presented at that time.

The Panel noted that the applicant's claim of superiority of the SenSura Mio product range was based on:

- the presence of an elastic adhesive in the double layer baseplate, which, it claimed, allows for physical activity and is better able to mould to different body shapes; and
- a full circle filter, which helps reduce incidents of ballooning.

In support of the claim of superiority, the applicant presented two main studies, CP2110C – Clinical Investigation of filter improvement for new filter to ostomy bags – Morfeus; and CP232 – Investigation of new developed 1 and 2 piece convex ostomy products in subjectts with ileostomy.

Study CP2110C included a cross-over study which examined the frequency of ballooning and the time to ballooning when testing products with the new filter (Morfeus) compared to the existing SenSura filter. A trial involving 20 subjects with ilestomies tested each product for 14 days. Results indicated that ballooning occurred in 55% of the reference product and 26% with the Morfeus filter. Pancaking and odour was not different for the two products.

Study C232 was a randomised controlled trial of a new convex baseplate compared to an existing Coloplast baseplate, SenSura Convex. It was a randomised controlled two way cross-over study, with each phase lasting 28 days. It involved 129 subject patients with an ileostomy. The primary endpoint was the degree of leakage under the baseplate on a 32

point scale. Secondary endpoints included leakage on clothes, wear time, use of accessories and reason for changing appliance. The panel noted that the differences in the score for leakage under the base plate was 0.7 whereas the non-inferiority margin was stated to be -2.5 points. There was no significant difference between any of the other endpoints using objective measures including leakage outside the baseplate, DETscore, peristomal disease, base plate or the use of accessories. The patients reported an increased quality of life of -10 on a 0-92 point score. The only significant difference in any of the endpoints is leakage under the base plate which while statistically significant is unlikely to be clinically relevant. In regard to adverse events a higher percentage of the participants reported an event with the MIO product-22.4% reported skin and subcutaneous tissue disorders with MIO compared to only 11.7% with the Sensura product. The relationship between any of the endpoints, including adverse events, and the higher HRQoL measure is problematic.

The Panel noted that there appears to be little justification regarding the superiority of this product to its comparator. In relation to CP2110C, the Panel agreed that given that the AF300 filter has a price premium of $0.274, this product may have been a more appropriate comparator to nominate to address the issue of filter performance as a formal basis of the claim for a price premium. To compare two filters which do not include the AF300 filter is non-informative.

The Panel agreed that in essence, while there may be a benefit of the new SenSura filter over the old SenSura filter, the quantification and monetary value of that benefit is highly uncertain and its comparison with the AF300 filter is unknown.

In relation to study CP232, the Panel agreed that the differences in leakage are small and the evidence does not support superior clinical outcomes. The Panel also agreed that there was no significant difference between baseplates and therefore no justification for a price premium based on the baseplate. The economic analysis presented, based on disutility measures for nocturia, results in a high and uncertain cost effectiveness ratio eg no disutility is given for the significant increase in adverse skin reactions for MIO.

There is therefore no basis provided within the current submission for the granting of a premium over the base-price products in the subgroup.

Economic Analysis
Not undertaken.

Financial Analysis
Not undertaken.

6. SPAP Recommendation

The SPAP recommended that the applicant's request for the addition of a $0.953 per unit price premium to the SenSura Mio One-Piece Deep Convexity Drainable (SAS code 80040P), currently listed in subgroup 2(b) of the SAS Schedule, be rejected due to an inadequate evidence base in support of the claim of product superiority.

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

Coloplast agrees with SPAP's recommendation.