PUBLIC SUMMARY DOCUMENT

Product: SenSura One-Piece Closed Flat Pouch
Applicant: Coloplast Pty Ltd
Date of SPAP Meeting: 12-13 November 2012

1. Proposed listing on the Stoma Appliance Scheme

The applicant, Coloplast, sought a continued listing of the SenSura One-Piece Closed Flat Pouch in Subgroup 1(b) of the SAS Schedule. The applicant proposed a unit price of $3.124 which includes a price premium of $0.389 (or 14%) over the benchmark price ($2.735) for one-piece closed pouch with a flat skin barrier.

A price premium was claimed to be justified due to the incorporation of two features that were claimed to result in a superior health outcome: (i) a baseplate claimed to have improved flexibility and tack/adhesion resulting in reduced leakage, and (ii) an enhanced filter (known as the Morpheus filter) resulting in improved airflow.

The applicant nominated a product from Hollister, the ModermaFlex One-Piece Closed Flat Pouch which is currently listed in Subgroup 1(b) of the SAS Schedule at a unit price of $2.735 (SAS Code: 3934C), as the comparator.

2. Background

The SenSura One-Piece Closed Flat Pouch has been listed in Subgroup 1(b) of the SAS Schedule at a unit price of $3.233 (SAS Code: 9830J), with 16 variants and a maximum quantity of 90 units per month, since April 2011.

3. SPAP Comment

Clinical Place for the Product

SPAP agreed that there is a clinical need for products with improved baseplates and for products with improved filters. The application contended that a large proportion of cases of peristomal skin complications are attributable to leakage under the baseplate, which results in contact between corrosive stoma effluent and the skin. SPAP agreed that peristomal skin disorders have direct consequence for a patient's quality of life and agreed that an optimally performing baseplate can result in the reduction of the risk and severity of peristomal skin complications.

Clinical Analysis

i) Baseplate leakage/skin condition

The applicant presented three studies: DK109OS (reported by Voergaard et al., 2006); DK1450S (Teniere et al., 2007); and DK175OS, to support the claim for the superiority of the baseplate over the comparator. Two of the studies (DK109OS and DK1450S) were open label, randomised, cross-over studies comparing the SenSura one-piece pouch with two separate currently listed one-piece pouches. The other study was a non-comparative study investigating the change in the rate of peristomal skin complications following the use of a product from the SenSura range.

The Panel noted that the published reports of the open label cross-over studies indicated that skin evaluations were similar using both bags and similar to the skin evaluations at baseline. In relation to the frequency of leakage, Voergaard et al., 2006 reported that the frequency of leakage corresponded to the usual leakage frequency reported at baseline by this study

population. Teniere et al, 2007 did not present any data for rates of leakage. Therefore the SPAP considered that the evidence from these studies did not support a claim of superiority in terms of impact on leakage, which the SPAP accepted as a contributing factor to peristomal skin condition.

The Panel also discussed the fact that higher rates of preference for the SenSura product than for the reference product were reported. However, the SPAP considered these outcomes to be subjective outcomes, and given the open label design of the trial, the potential for bias in the results could not be excluded.

The Panel also noted that the application purports that the improved tack and flexibility of the baseplate contributes to less leakage, however, the evidence provided was insufficient to substantiate this claim.

The panel discussed the third study (DK1750S) and agreed that, as a non-comparative study, this study did not provide information to assist in the determination of the comparative performance of the SenSura product with reference products. The SPAP noted that as patients were not restricted to using their usual type of device during the study, confounding of results as a consequence of patients changing the type of device used (e.g. from a flat to convex baseplate) could also not be excluded.

The panel also noted that participants were given advice on maintaining healthy peristomal skin in addition to the provision of the SenSura appliance. For this reason, the SPAP could not differentiate between the impact of the advice from the impact of the appliance on results and the assertion that evidence-based nursing was not a cause for improvement could not be assessed.

ii) Filter performance

The applicant presented five studies as evidence to support the claim of the superiority of the filter, three being open label, randomised, cross-over studies (the two studies described above and CP201OC) and two being laboratory tests comparing the new SenSura filter with the old SenSura wave filter and Hollister's AF300 filter.

In relation to the DK109OS and DK1450S studies, the SPAP noted that these studies were undertaken prior to the global launch of the AF300 filter in August 2007. Therefore, the SPAP considered it unlikely that the Nova 1 or ModermaFlex comparator products in these studies would have included the advanced filter.

The panel noted that a statistically significant reduction in the frequency of ballooning was found for the Sensura product versus the reference product in study CP201OC, with p-value=0.016 and a 29% reduction in ballooning events (95% CI: 6%-46%). The time to ballooning was 32% longer for the test product than for the reference product, with p-value<0.001 (95% CI: 16%-49%).

The Panel was also unsure as to why studies CP210OC and CP211OC (described at clinicaltrials.gov) were excluded from presentation in the application. Both of these studies compared the new filter with the old filter in the SenSura product and would have been relevant to the SPAP's consideration of the comparative performance of the new filter with the old. The SPAP thus considered that the evidence base for assessing the comparative performance of the new filter presented in the application was incomplete.

The Panel discussed the results of the laboratory study which indicated superior air flow for the AF300 versus the new SenSura filter until contamination of the filter but better air flow for the new SenSura filter after two contaminations of the filter. It was noted that the contamination event was produced artificially and therefore the impact of contamination on

filter performance and patient QoL in practice was not adequately demonstrated. The application did not discuss the likelihood of contamination of the filter in practice and did not investigate the impact of such contamination on the user (e.g. users generally change a one-piece bag three times daily so contamination may not be a significant issue for this subgroup).

4. SPAP Recommendation and Reasons

The Panel recommends that Coloplast's request for a price premium of $0.389 per unit for its currently listed SenSura One-Piece Closed Flat Pouch (SAS Code 9830J) is rejected due to insufficient evidence to support the claim for a premium.

5. Applicant's Comment

Coloplast acknowledges the above recommendation and will re-submit accordingly