

## PUBLIC SUMMARY DOCUMENT

**Product:** Sensura Mio Products  
**Applicant:** Coloplast Pty Ltd  
**Date of SPAP Meeting:** 20 October 2020

### 1. Proposed Listing on the Stoma Appliance Scheme

The applicant, Coloplast Pty Ltd, sought the addition of a price premium to the following SenSura Mio products currently listed on the SAS Schedule:

Table 1

Subgroup	SAS Code	Product
1b	3991C	SenSura Mio One Piece Closed Flat
1c	80037L	SenSura Mio One Piece Shallow Convexity Closed
1c	80038M	SenSura Mio One Piece Deep Convexity Closed
1c	80045X	SenSura Mio One Piece Shallow Convexity Closed
2a	3998K	SenSura Mio One Piece Drainable Flat
2b	80039N	SenSura Mio One Piece Shallow Convexity Drainable
2b	80040P	SenSura Mio One Piece Deep Convexity Drainable
2b	80041Q	SenSura Mio One Piece Soft Convex Drainable
5a	80014G	SenSura Mio Two Piece Closed Click Mechanical Coupling
5b	80015H	SenSura Mio Two Piece Closed Pouch Adhesive Coupling
6a	80026X	SenSura Mio Two Piece Drainable Click – Mechanical Coupling Pouch
6b	80012E	SenSura Mio Two Piece Drainable Flex – Adhesive Coupling

### 2. Comparator

The applicant has nominated Hollister and Dansac comparator products in the appropriate subgroups.

### 3. Background

This was the Stoma Product Assessment Panel's (SPAP) third consideration of these products.

#### 4. Clinical Place for the Product

The proposed products provide an alternative for users in each subgroup.

#### 5. SPAP Comment

##### *Clinical Analysis*

The SPAP noted that the applicant had presented numerous studies in support of the application. The applicant provided real world data (RWD) from a UK study comparing the submitted product with a product containing a filter for which the Panel had previously recommended a price premium. Outcome measures included incidence of ballooning, leakage, social concern, odour and pancaking. The analysis of the RWD involved propensity adjustment for baseline characteristics. Laboratory testing on flow rates through the filter under various conditions was also presented.

The Panel considered that the data presented by the applicant supported the claim that the performance of the filter contained in the Mio range was no worse than that of the AF300 filter for which a current price premium is applied. The premium varies with different types of products as shown in Table 2 below.

##### *Economic Analysis*

The Panel noted the economic analysis presented by the applicant in support of the price premium.

##### *Financial Analysis*

Including the addition of the price premium to the currently listed SenSura Mio product range this would result in a cost to Government. It is therefore, likely there would be a budgetary impact for the SAS as a consequence of the addition of the price premium.

#### 6. Recommendation

The SPAP recommended that the application for the addition of a price premium to the existing SenSura Mio products in the subgroups as per the Table 2 below.

Table 2; Recommended premiums

<b>Subgroup</b>	<b>SAS Code</b>	<b>Product</b>	<b>SPAP Recommendation</b>	<b>Price Premium</b>
1b	3991C	SenSura Mio One Piece Closed Flat	Recommended	\$0.274
1c	80037L	SenSura Mio One Piece Shallow Convexity Closed	Recommended	\$0.274
1c	80038M	SenSura Mio One Piece Deep Convexity Closed	Recommended	\$0.274
1c	80045X	SenSura Mio One Piece Shallow Convexity Closed	Recommended	\$0.274
2a	3998K	SenSura Mio One Piece Drainable Flat	Recommended	\$0.205
2b	80039N	SenSura Mio One Piece Shallow Convexity Drainable	Recommended	\$0.205
2b	80040P	SenSura Mio One Piece Deep Convexity Drainable	Recommended	\$0.205
2b	80041Q	SenSura Mio One Piece Soft Convex Drainable	Recommended	\$0.205

5a	80014G	SenSuraMio Two Piece Closed Click Mechanical Coupling	Recommended	\$0.205
5b	80015H	SenSura Mio Two Piece Closed Pouch Adhesive Coupling	Recommended	\$0.205
6a	80026X	SenSura Mio Two Piece Drainable Click – Mechanical Coupling Pouch	Recommended	\$0.205
6b	80012E	SenSura Mio Two Piece Drainable Flex – Adhesive Coupling	Recommended	\$0.205

### **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 the Panel's recommendation.