

## PUBLIC SUMMARY DOCUMENT

**Product:** Peristeen Plus  
**Applicant:** Coloplast Pty Ltd  
**Date of SPAP Meeting:** 26 April 2022

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

The applicant, Coloplast Pty Ltd, sought listing of the Peristeen Plus system, with 3 components, in subgroup 8(b) of the Stoma Appliance Scheme (SAS) Schedule. The product was proposed for listing at an annual price and maximum quantity as indicated in Attachment A.

### 2. Comparator

The applicant nominated standard medical management (SMM) as the comparator. The Panel considered this was appropriate and noted there is no comparable product currently available on the SAS.

### 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 provides a product for users with anorectal malformations or imperforate anus aged 3 years or over. Peristeen Plus is indicated for patients who have continued faecal incontinence where SMM therapies of oral laxatives and retrograde enemas have failed (claimed in the submission to be approximately 40% of patients).

### 5. Clinical Analysis

The submission presented a meta-analysis of five clinical studies. The Panel acknowledged there is limited evidence for use of Peristeen Plus in faecal incontinence. The submission noted the use of Peristeen Plus is for patients who experience failed treatment with SMM and delays the requirement for surgical treatment. The meta-analysis indicated an approximate 60% reduction in faecal incontinence and a 50% reduction in constipation at 3 months. An improved quality of life at 3 months was reported in patients using Peristeen Plus but this was not present at 12 months. The sponsor stated that the reduction in utility gain over time was likely due to patients resetting their expectations because of other complications associated with anorectal malformations.

The Panel considered patient education would be required for the use of Peristeen Plus in patients to ensure it is being used safely and appropriately, and noted the applicant included an educational strategy in the submission.

### 6. Economic Analysis

The submission presented a population-based lifetime Markov economic model to simulate one-year cycles. The Panel considered the application of the utility gain seen at 3 months to all cycles of the model was not appropriate and caused uncertainty in the cost effectiveness. The Panel noted the significant sensitivity of the cost effectiveness estimate

to the frequency of use in the economic model. A discount rate of 5% was applied in the model, which the Panel considered appropriate.

## **7. Financial Analysis**

The Panel noted the total cost of the Peristeen Plus system was sensitive to frequency of use and patient uptake rate. The Panel noted the incidence population is uncertain, adding to the uncertainty of cost to Government. The Panel also recognised the approach of using different packs of components which would be a challenge for the Stoma Associations to administer to ensure that appropriate utilisation of the product.

## **8. SPAP Recommendation**

The Panel deferred making a recommendation on the Peristeen Plus system. The Panel acknowledged the submission was comprehensive but noted that adjustments were required to the economic model to reduce uncertainty in the cost. The Panel noted the clinical need for the product in patients in the nominated population, but that restrictions would be required to ensure the product is used safely and limited to the intended population. The Panel indicated that they would welcome a resubmission from the applicant which addresses the issues of uncertainty in the economic model and its impact on the cost effectiveness and the factors which may impact on the uncertainty of the total cost.

## **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**

**Attachment A**

**Table 1: Proposed annual unit price for the Peristeen Plus system**

Product code	Pack quantity	Recommended replacement periods (number of uses)	Proposed maximum quantity/year (for daily use)	Price per pack	Cost per year by frequency of use		
					Daily	Second day	Third day
29140	1	Pump = 90	4				
	1	Lid = 90					
	1	Water bag = 15					
	2	Catheter = 1					
29142	1	Water bag = 15	20				
	15	Catheter = 1					
29143	10		60				

Source: page 30 of the submission