Australian Government
Department of Health and Aged Care

Stoma Appliance Scheme Schedule Review - Terms of Reference

Objective

Products listed on the Stoma Appliance Scheme (Scheme) Schedule should reflect principles of maximising health outcomes for ostomates while maintaining the sustainability of the Scheme. The aim of a review of the Scheme Schedule is to ensure products listed are clinically appropriate, priced appropriately and cost-effective.

Background

The Scheme was established in 1975 to support people with a stoma (ostomates) and provides fully subsided access to around 4,000 stoma appliances and products to help them live normal lives. In 2022-2023, the Scheme supported around 49,000 ostomates with an average annual cost per ostomate of subsidised products being over $2,300.

Sponsors apply to have their products listed on the Scheme Schedule according to the Application and Assessment Guidelines. The Stoma Product Assessment Panel (SPAP), an independent technical advice panel appointed by the Department, evaluates new products for approval for listing on the Scheme Schedule.

The current 1 April 2023 Scheme Schedule is available on the Department's website at: https://www.health.gov.au/resources/publications/stoma-appliance-scheme-schedule.

While there have been reviews of specific sub-groups or products on the Scheme Schedule, there has been no comprehensive review of all products, pricing and groups since 2010. There has been a rapid expansion of products listed, with around 4,000 currently listed compared to 2,200 in 2010. Many products currently listed have minimal utilisation and limited clinical evidence to support their use and are potentially priced inappropriately.

Scheme clinical eligibility

The current Ministerially approved clinical eligibility in the Scheme's Operational Guidelines provides access to people who:

- *have a temporary or permanent artificial body opening (created surgically or otherwise, including a fistula that originates from the urinary or gastrointestinal tract) which facilitates the removal of urine and/or products of the gastrointestinal tract from the body where the person does not have normal gastrointestinal tract or bladder functions*.

Clinical eligibility for the Scheme has been reviewed periodically due to advances in surgery and for specific conditions. For example, in 2021, the then Minister for Health agreed that patients with a neo-anus opening created due to anorectal malformation (ARM) or imperforate anus (IA), Malone Antegrade Continence Enema (MACE) and Mitrofanoff stoma subtypes meet the eligibility requirements for the Scheme.

The review is to consider the current clinical eligibility to ensure it reflects the principles and intent of the Scheme and if stomas formed outside the gastrointestinal tract, and/or stomas that do not facilitate the removal of waste products should be included. The review is also to consider whether there is duplication with the support provided to patient cohorts in other government subsidy schemes.

Scheme Schedule structure

The current Scheme Schedule has around 4,000 product variants listed under around 600 separate codes (known as SAS Codes). Products are categorised into 11 product type groups and 38 sub-groups.

Stoma Appliance Scheme Schedule Groups and Subgroups Table

Group Number	Main Group	Subgroup
1	One-Piece Closed	(a) Stoma Caps (b) Flat Baseplate (c) Convex Baseplate
2	One-Piece Drainable	(a) Flat Baseplate (b) Convex Baseplate
3	One-Piece Urostomy	(a) Flat Baseplate (b) Convex Baseplate
4	Two-Piece Baseplate	(a) Mechanical Coupling – Flat (b) Mechanical Coupling – Extended Wear (c) Mechanical Coupling – Convex (d) Adhesive Coupling – Flat (e) Adhesive Coupling – Extended Wear (f) Adhesive Coupling – Convex
5	Two-Piece Closed	(a) Mechanical Coupling (b) Adhesive Coupling
6	Two-Piece Drainable	(a) Mechanical Coupling (b) Adhesive Coupling
7	Two-Piece Urostomy	(a) Mechanical Coupling (b) Adhesive Coupling
8	Alternative Systems	(a) Plug Systems (b) Irrigation (c) Catheters (d) Rubber Appliances
9	Accessories	(a) Adhesive Barrier (b) Belts (c) Clamps and Clips (d) Cleansers and Solvents (e) Convexity Inserts (f) Creams and Ointments (g) Deodorants (h) Hernia Support Belts and Garments (i) Night Drainage (j) Powders and Pastes (k) Protective Films (l) Seals (m) Miscellaneous
10	Paediatric	(a) All
11	Fistulae	(a) All

The review is to consider the current Scheme Schedule structure and particularly the:

- structure and names of each of the Scheme Schedule groups and subgroups to ensure they reflect the appropriate clinical products required by ostomates
- deletion of Scheme Schedule groups or subgroups not reflective of current clinical use, where products are unlikely to support improvements in health outcomes, or where subsidy is not appropriate for other reasons.

Pricing and maximum quantities of products

Current pricing and maximum quantities of products in each of the Schedule groups are:

- Groups 1 to 7 have a formal benchmark or price premium pricing
- Groups 8 to 11 prices and restriction quantities are determined by the SPAP.

The review is to consider the pricing of products, including:

- the timing of, or need for, periodic pricing reviews
- consideration and cost analysis of other cost models such as annual indexation, anniversary price reductions and/or reference pricing across a product group.

Review Scope

Phase One

The first phase of the review to include:

a. Scheme clinical eligibility

1. Consider and assess the current clinical eligibility and recommend changes, if any, to ensure it reflects the principles and intent of the Scheme.
2. Investigate and identify patient numbers and an indicative estimate of costs of including in the Scheme people with stomas that occur outside the gastrointestinal tract, and/or stomas that do not facilitate the removal of waste products from the gastrointestinal tract.
3. Investigate and identify support provided to various patient cohorts under other government subsidy schemes such as the National Disability Insurance Scheme (NDIS), Continence Aids Payment Scheme (CAPS) and state-based equipment schemes to avoid duplication of support.
4. Identify and recommend initiatives to improve access to the Scheme for marginalised groups such First Nations peoples and Culturally and Linguistically Diverse (CALD) groups together with rural and remote ostomates.

b. Scheme Schedule structure

5. Consider the current Scheme Schedule groups and sub-groups and recommend changes, if any, to reflect current clinical practice.
6. Consider the names of the current Scheme Schedule groups and sub-groups and recommend changes, if any, to reflect current clinical practice.
7. Consider whether any current Scheme Schedule groups or sub-groups should be deleted or modified to reflect current clinical practice or because they are not appropriate for Government subsidy.

c. Pricing and maximum quantities of products

8. Consider the current methodology for pricing of products and recommend changes, if any, to align with other health technology assessment methods and health technology subsidy schemes.
9. Consider alternative approaches to price setting of products, including the suitability of a tendering approach such as is used for the National Diabetes Services Scheme.
10. Identify any pricing and maximum quantities allowances listing anomalies in the current process for listing on the Scheme Schedule and recommend changes, if any, to ensure consistency.
11. Investigate the timing of, or need for, periodic price reviews and recommend changes, if any, to ensure appropriateness of prices for products.
12. Investigate and analyse other cost models and recommend changes, if any, to align with other health technology assessment methods and health technology subsidy schemes in Australia and internationally. This may include for example, annual indexation, anniversary price reductions and/or reference pricing across a product group.
13. Identify estimates of budgetary implications for other cost models.

Phase Two

Phase Two is to draw on the outcomes of the first phase and assess all currently listed products based on the agreed recommendations from Phase One, including:

14. Consider and recommend changes to any currently listed products in respect to:
    a. their inclusion in the appropriate group or subgroup
    b. appropriate maximum quantities and restrictions that are reflective of clinical practice to ensure ostomates have access to sufficient quantities while also minimising wastage through oversupply
    c. their clinical efficacy, appropriateness, and cost-effectiveness
    d. analysis of utilisation particularly those with minimal use
    e. appropriateness for inclusion on the Schedule and ongoing subsidy.
15. Consider and recommend changes to pricing or maximum quantities of individual products to ensure appropriate prices for products remaining on the Schedule.
16. Investigate and recommend timeframes for regular periodic Schedule reviews by the SPAP based on timing, utilisation or costs of products or a combination of these. This would include review of utilisation and expenditure of products, either on an individual, group or subgroup basis over the last decade, or timing of when accurate data is available.

Timeframe

It is expected that the review and any recommendation of appropriate changes to the Scheme Schedule for Government consideration would be undertaken in two phases. The first phase is to be completed by early 2024, noting outcomes may require Government endorsement before proceeding with the second. The second stage is expected to be completed by the end of 2024 and will include further recommendations for Government consideration.