Australian Government
Department of Health and Aged Care

This paper was published to inform a public consultation process that ran from 2 September 2024 to 6 October 2024. The consultation is now closed.

Stoma Appliance Scheme Schedule Review – Consultation Paper

September 2024

Contents

Introduction

The 2023-24 Budget included agreement to a comprehensive review of the Stoma Appliance Scheme (SAS) Schedule. The aim of the SAS Schedule Review (the Review) is to make sure all the products listed are clinically effective, correctly priced, and cost-effective. While there have been reviews of specific sub-groups or products on the SAS Schedule, there has been no comprehensive review of all products, pricing and groups since 2010.

The Review is focusing on:

- the intent of the SAS
- SAS Schedule structure
- clinical eligibility for the SAS, and
- product pricing.

The Review aims to result in an updated SAS Schedule that prioritises improving health outcomes for people with stomas (ostomates) while also ensuring the SAS remains sustainable into the future.

Purpose of this paper

The purpose of this paper is to inform stakeholders and seek their views regarding the proposed changes to the SAS and SAS Schedule. This paper provides the:

- background to the SAS and the Review
- proposed changes to the SAS and SAS Schedule, and
- rationale for the proposed changes to the SAS and SAS Schedule.

The Department of Health and Aged Care (Department) wants to work with all stakeholders to ensure the SAS is fit for purpose, serves the needs of all ostomates, and protects the future sustainability of the SAS.

Background

Stoma Appliance Scheme

The SAS was established in 1975 to support ostomates. It provides fully subsided access to stoma appliances and products to help ostomates live normal lives. In 2023-2024, the SAS supported around 50,000 ostomates, with an average cost of subsidised products of over $2,300 per ostomate.

Product sponsors apply to have their products listed on the SAS 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 listing on the SAS Schedule and provides advice on other SAS matters.

The current SAS Schedule is available on the Department's website.

There has been a rapid expansion of products listed on the SAS Schedule, with 3,430 products currently listed (July 2024) compared to 1,956 in 2012. The cost of the SAS has also increased, from $83.3 million in 2012-13 to $114.5 million in 2023-24. Some products currently listed have minimal utilisation, while others have limited clinical evidence to support their use. In addition, pricing for most products has not been reviewed since 2012.

Current SAS Schedule Structure

The current SAS Schedule has 3,430 products listed under 569 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

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

Product pricing, maximum quantities, and restrictions

Product Pricing

Product prices on the SAS Schedule are set by the Government following advice from the SPAP. Products in Groups 1 to 7 are priced according to a benchmark price or a price premium. The Government has defined a benchmark price for each subgroup in Groups 1 to 7, which allows products to be priced consistently and appropriately. Products that are equivalent in terms of features, safety and clinical effectiveness to a benchmark product already listed on the SAS Schedule are listed at the benchmark price. If a product has features providing an additional clinical benefit, the product may be eligible to be listed at a higher price than the benchmark price. The SPAP will recommend a price premium where evidence supports that the product offers an improved outcome over the benchmark product. The price premium reflects the additional benefit(s) the product offers in relation to clinical effectiveness and/or safety.

Products in Groups 8 to 11 do not have set benchmark prices. Prices for these products are based on recommendations by the SPAP after consideration of the strength and quality of the evidence provided by the product sponsor in their application. Pricing may be informed by the price of other similar products already listed on the SAS Schedule.

Maximum Quantities

Each product on the SAS Schedule has a maximum quantity, which is recommended by the SPAP to reflect clinically appropriate usage. This can be a monthly or an annual maximum. If an ostomate needs more than the maximum quantity of a product to manage their stoma, the ostomate can apply to their stoma association to order additional supplies, after consultation with their authorised health professional[1]. When multiple products that serve the same purpose are requested, the maximum amount supplied of each product must be reduced to ensure supply limits are not exceeded. For example, if 2 functionally equivalent adhesive removers are requested, the maximum quantity of each would be reduced by 50%.

Some products have a restriction that means only the maximum quantity can be ordered, with no additional supplies.

Restrictions

Certain products on the SAS Schedule are also subject to access restrictions. The SPAP recommends whether an access restriction should be applied to a product. Where a product is subject to a restriction, this will be identified as part of the product description on the SAS Schedule. The 4 types of restriction are detailed in the table below.

Restriction	Definition
R1	Requires authorisation by a Stomal Therapy Nurse (STN), nurse practitioner, registered nurse or registered medical practitioner.
R2	No authority for an increase in the yearly allocation can be granted.
R3	Strict Usage Restriction – Requires authorisation by an STN, nurse practitioner, registered nurse or registered medical practitioner including clinical justification.
R4	Strict Usage Restriction – Requires authorisation by a colorectal or general surgeon.

[1] An authorised health professional in the SAS is a STN, nurse practitioner, registered nurse or registered medical practitioner.

Maximum quantities and restrictions aim to ensure ostomates are using the most appropriate product for the management of their stoma, and to reduce over-ordering and potential product wastage.

The Review

Review work completed to date has included a report by an external consultant (HealthConsult). The HealthConsult report was prepared to inform the SPAP's consideration and recommendations and government decision making. This report:

- assessed the current clinical eligibility to ensure it reflects the principles and intent of the SAS
- investigated possible inclusion of stomas that occur outside the gastrointestinal tract, and/or stomas that do not facilitate the removal of waste products
- investigated support provided under other government subsidy schemes (national and state/territory) to identify any duplication in current eligibility or potential expanded eligibility, and
- assessed methodology for pricing of products and cost models and considered periodic reviews to align with other health technology assessment methods and subsidy schemes.

This consultation paper has been informed by the HealthConsult report and recommendations from the SPAP. Further information on these recommendations is below.

Recommendations for reform

The SPAP considered current issues with the SAS Schedule, drawing on their knowledge of the SAS, stakeholder feedback on the SAS Schedule, the HealthConsult report and advice from the Department. The SPAP agreed the SAS should continue to support ostomates by providing fully subsidised access to stoma related products, including access to products that are clinically necessary for the management of a stoma incorporating those that improve ostomates' quality of life. The SPAP noted findings in the HealthConsult report that the SAS has adapted well to advancements in surgical techniques and medical conditions and does not duplicate or overlap with any other national or state/territory funded medical appliance or equipment schemes.

To ensure all products listed on the SAS Schedule are clinically effective, cost-effective, and priced appropriately, the SPAP and the Department have developed the following 4 recommendations for public consultation.

Recommendation 1: Eligibility

The SAS should maintain its focus on stomas originating from the urinary and gastrointestinal tract for the removal of waste. The current eligibility criteria should not expand to cover non-gastrointestinal stomas and stomas not for the removal of waste.

Rationale

The SAS currently supports people with a stoma, defined as:

> *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*.

Not all stoma types are currently in scope for the SAS. Stoma types not currently in scope include:

- tracheostomy – a hole through the front of the neck and into the windpipe, to help air and oxygen reach the lungs
- gastrostomy – an opening into the stomach from the abdominal wall, made surgically for the introduction of food and/or medication, or the release of gastric pressure
- thoracostomy – an incision in the chest wall, commonly used for treatment of a pneumothorax
- pharyngostomy – a hole or opening in the throat or neck to insert a tube to facilitate feeding when patients cannot eat by mouth for a short period.

The HealthConsult report recommended the SAS should maintain its focus on stomas originating from the urinary or gastrointestinal tract for the removal of waste, including fistulas and biliary stomas. The report recommended the SAS should refrain from expanding eligibility to cover non-gastrointestinal stomas or where a stoma is not for the removal of waste. In many cases, support is available for other stoma types through state/territory-based schemes and/or the National Disability Insurance Scheme (NDIS). Some other stoma types are usually created for short-term condition management and are managed in hospital settings.

While management of some other stoma types, and other conditions such as wounds requiring drainage, may use some products currently listed on the SAS Schedule, the SPAP noted the importance of maintaining the original intent of the SAS to help ensure the long-term sustainability of the program. It noted there are other national and/or state/territory funded programs to support people with non-gastrointestinal stomas or other conditions requiring similar products.

The SPAP specifically considered the inclusion of neo-anus openings in the eligibility criteria. Since 2021, there has been agreement that patients with a neo-anus opening created due to anorectal malformation or imperforate anus meet the eligibility requirements for the SAS. The SAS Schedule currently includes transanal irrigation products for children aged 3-17 years old who have a neo-anus opening created due to anorectal malformation or imperforate anus.

The HealthConsult report recommended retaining neo-anus openings in the SAS eligibility. However, the SPAP noted that having a neo-anus opening created due to anorectal malformation or imperforate anus does not meet the current eligibility criteria of the SAS. People with anorectal malformation or imperforate anus may have a colostomy while awaiting or recovering from surgery to correct the malformation and are eligible to access the SAS for products to manage their stoma. However, it may not be appropriate to continue to include products on the SAS Schedule for managing continence once the colostomy is reversed and stools can be expelled through the anus.

Transanal irrigation products are not available on the SAS for people with other conditions such as neurogenic bowel dysfunction who suffer from faecal incontinence, chronic constipation, and/or time-consuming bowel management procedures, who may benefit from these products. There is no suggestion that SAS eligibility should be expanded for people with these conditions.

Access to transanal irrigation products may be better supported through other schemes, including the NDIS for eligible participants, the Continence Aids Payments Scheme, and state/territory equipment schemes.

The HealthConsult report noted there are sometimes differences in interpretation and application of the SAS eligibility criteria. The SPAP agreed it would be appropriate to publish a list of stoma types meeting SAS eligibility requirements, to support health professionals and stoma associations to understand the scope of the SAS and ensure consistency in access.

Questions:

Do you agree the SAS should maintain its focus on stomas originating from the urinary or gastrointestinal tract for the removal of waste? Why?

If you consider that the scope of the SAS should be expanded, what other stoma types or conditions do you think should be included? Why?

If the scope of the SAS is expanded, what measures would you suggest putting in place to ensure the SAS remains sustainable?

Should neo-anus openings following corrective surgery for anorectal malformation or imperforate anus be included in the SAS clinical eligibility? Why?

Recommendation 2: Maximum quantities

Review the current maximum quantity restrictions on all products to ensure these are in line with clinical requirements.

Rationale

Each product listed on the SAS Schedule has a listed monthly or annual maximum quantity. These maximum quantities are recommended by the SPAP taking into account what an ostomate would normally require to manage their stoma.

The HealthConsult report identified that there are currently anomalies in maximum quantities for some listed products, where SAS Schedule maximum quantities do not align with clinically recommended use of some products. For example, for products listed in subgroup 1c (Convex Baseplates), it is recommended the bag could require changing up to 3 times per day, but the current maximum quantity for most products in this subgroup is 60 per month. A more appropriate maximum quantity would be 90 per month so ostomates who use this product can change the bag 3 times a day without requesting additional supplies.

Conversely, for some SAS Schedule products, the maximum quantity may be too high, which may lead to over-ordering and product wastage.

The SPAP recommended that current maximum quantity restrictions for all products should be reviewed to ensure these reflect clinical requirements. This is likely to mean that some products will have a change to their maximum quantities. The aim of these changes would be to ensure the maximum quantities reflect the quantity needed by most ostomates to manage their stoma. In some cases, this would be higher than the current maximum quantity, but for other products it may be lower. If an ostomate needs more than the maximum quantity after the changes, they would still be able to apply through their stoma association to access additional supplies for most products, similar to the current process.

Question:

Are you aware of any products on the SAS Schedule where the maximum quantity restrictions do not align with the amount required for clinically recommended use of the product? If yes, please list the products or types of products, their maximum quantities and an explanation for your answer. (Note: this could include maximum quantities that are too low, with not enough products provided, or too high, with too many products available each month/year.)

Recommendation 3: Group 9 products

Group 9 (accessory products) should be split into 2 groups to differentiate between products that are necessary to manage a stoma and those that are discretionary. Products considered to be discretionary should have higher evidence requirements for listing and stricter maximum quantities and restrictions.

Rationale

Group 9 (accessory products) includes adhesive barriers, belts, clips, cleansers and solvents, convexity inserts, creams and ointments, deodorants, stoma support belts and garments, night drainage, powders and pastes, protective films, seals, and other miscellaneous accessory products. Group 9 has the largest number of dispensed products by group, accounting for 52.5% of the total volume of products dispensed in 2023-24.

The HealthConsult report noted that rationalising products on the SAS Schedule would help to minimise wastage and optimise expenditure. The HealthConsult report suggested removing products that may not be clinically necessary, such as cleanser wipes, deodorants, and creams and ointments.

The SPAP's view was that, while all products in Group 9 are relevant to stoma management and may assist ostomates in the management of their stoma, some products are not clinically necessary for stoma management and/or are not being used in a clinically appropriate manner, which could contribute to stoma management problems.

The SPAP has therefore proposed Group 9 products be split into 2 groups:

1. Products that are clinically necessary for stoma management, based on accepted clinical practice in stoma management.
2. Discretionary products that are used by ostomates as a preference, but which are not clinically necessary. Products in this group will have higher evidence requirements for listing on the SAS Schedule and stricter maximum quantities and restrictions.

Under this proposal, *'Discretionary Products'* would still be available on the SAS Schedule but may have lower maximum quantities and further restrictions on ordering. For example, an ostomate may need an authorised health professional[2] to approve the use of a product in this category. In addition, sponsor applications to list new products in this category would require additional evidence to support the benefit of these products to ostomates, and pricing may reflect the discretionary nature of these products. It is important to note ostomates would still be able to purchase these products privately.

[2] An authorised health professional in the SAS is a STN, nurse practitioner, registered nurse or registered medical practitioner.

The following split of Group 9 products has been proposed by the SPAP (current product group is listed in brackets):

Clinically Necessary Products	**Discretionary Products**
Tape, flange extenders, strips (subgroup 9a)	Protective sheets (subgroup 9a)
Pouch belts (subgroup 9b)	Lotions (subgroup 9d)
Clips (subgroup 9c) *	Cleanser wipes (subgroup 9d)
Adhesive remover sprays and wipes (subgroup 9d)	Creams and ointments (subgroup 9f)
Convex inserts (subgroup 9e)	Deodorants (not including deodorants that are also lubricants) (subgroup 9g)
Lubricants (including lubricating deodorants) (subgroup 9g)	Stoma support garments (subgroup 9h)
Night drainage (subgroup 9i)	Filters (subgroup 9m)
Powders and pastes (subgroup 9j)	Catheter straps (subgroup 9m)
Protective films (subgroup 9k)	
Seals (subgroup 9l)	
Absorbent powders/gels (subgroup 9m)	

* Only necessary for use with bags that do not have integrated closures.

Questions:

Do you agree with the proposal to split Group 9 products as described above? Why?

Do you have any comments regarding the proposed allocation of products to each category?

Recommendation 4: Product pricing

Maintain the current benchmark and premium pricing model for most products on the SAS Schedule and consider a price increase for products as well as regular pricing reviews.

Rationale

The current pricing model for the SAS uses benchmark and premium pricing to set product prices.

Benchmark pricing applies where the pricing for products considered to have similar features, safety and clinical effectiveness for pricing purposes is linked. The lowest priced product sets a benchmark price for equivalent products within the same subgroup. It allows new products to be listed on the SAS Schedule to be priced consistently and transparently in relation to existing products.

Premium pricing is a component of benchmark pricing. It provides flexibility for higher prices that have been justified for key features that provide improved outcomes, additional to those provided by the benchmark product. It also allows for access to a wider range of products.

The HealthConsult report considered the existing pricing model (benchmark and premium pricing) for stoma products alongside other pricing options such as tendering, negotiating and cost-based pricing. It found benchmark and premium pricing remains the most appropriate for the majority of products on the SAS. The report identified benefits of benchmark and premium pricing, including that it:

- is a well-established method of minimising costs
- is transparent, and
- supports a wide range of product choices.

The report identified that other pricing options would be less suitable for the SAS.

Negotiation is a common approach to set prices where products are supplied from private sector providers. It provides price flexibility in response to factors such base cost and clinical benefits. However, it is time consuming.

Cost-based pricing relies on identifying and measuring the costs associated with the development of products. It relies on the submission of cost data by suppliers, which can be challenging in competitive markets such as those involving the suppliers of products listed on the SAS Schedule.

Both negotiation and cost-based pricing were deemed unsuitable by HealthConsult for use on the SAS Schedule due to the administrative complexities involved in individual pricing of the extensive product range on the SAS Schedule.

Tendering involves specifying a range of products and inviting responses from the market to supply those products. Tenders may be evaluated on price only, or a combination of factors that lead to an overall ranking of suppliers that determines which will be offered supply contracts. Tendering is well suited to small groups of homogenous products. Stakeholders to the Review considered that tendering is not suitable for the majority of products on the SAS Schedule due to the need to maintain a broad range of products on the SAS Schedule to meet different ostomate needs, including type of stoma, body shape, stoma shape and size, stoma output amount, activity level, hand dexterity, and ostomate preferences.

The HealthConsult report also noted there have been no price increases since 2013, which is a significant concern for product suppliers.

The SPAP considered a price increase for some or all products on the SAS Schedule may be appropriate, alongside the introduction of regular pricing reviews.

While the benchmark/price premium approach appears to be the most suitable for the majority of the products on the SAS Schedule, there may be benefits in further exploration of a tendering approach for some or all the accessory products in Group 9, as there is less variation within the subgroups. This would mean a smaller range of available products in these categories, but greater efficiency in administration including streamlined product ordering for ostomates. There would be regular approaches to market for the relevant products to identify suppliers.

Questions:

Do you have any comments on the proposed approach to pricing of products on the SAS Schedule?

Do you have any comments about using a tendering approach for some or all products in Group 9?

Other comments

Thank you for your interest in the SAS and for taking the time to provide feedback on the proposed changes to the SAS Schedule. In addition to responses to the questions above, the Department would welcome any additional feedback in relation to the matters addressed in this paper, including clinical eligibility for the SAS, product availability, maximum quantities, restrictions or product pricing.

Question:

Do you have any other comments on the SAS Schedule, including in relation to clinical eligibility, available products, maximum quantities, restrictions, or product pricing?

Next steps

The outcomes of this consultation will inform the next phase of work on the Review. The outcomes will be considered by the SPAP and will inform its recommended changes to the SAS Schedule. Following Government consideration of the SPAP recommendations, any changes to the SAS Schedule would be communicated to stakeholders and the Department would work with stakeholders on the implementation of any changes.