Australian Government
Department of Health and Aged Care

Stoma Appliance Scheme

Application and Assessment Guidelines
July 2023

Contents

About this document

The Department of Health and Aged Care has prepared the Application and Assessment Guidelines to assist product sponsors applying to add new products to the Stoma Appliance Scheme Schedule or to vary or delete existing listings. This document was revised in 2022 to provide greater clarity around requirements and again in 2023 in conjunction with updates to application forms, and will be revised again as required. The Stoma Product Assessment Panel and Stoma Industry Association were consulted regarding the 2022 revisions to the document.

Part 1 – Introduction

1.1 Overview of the Stoma Appliance Scheme

The Stoma Appliance Scheme (the Scheme) is an Australian Government program that assists eligible people with stomas to better manage their condition by providing subsidised access to a range of different stoma-related products. The Scheme commenced in 1975 and is legislated under Section 9A of the *National Health Act 1953*. Products are distributed via stoma associations nationally. A person with a stoma who is eligible to access the Scheme must join one of these associations and pay an annual membership fee.

The Department of Health and Aged Care (the Department) and Services Australia administer the Scheme on behalf of the Government. The Department has policy responsibility for the Scheme and manages the Scheme Schedule (the SAS Schedule) and the product application and assessment process. It also provides secretariat support for the Stoma Product Assessment Panel (SPAP), the Department's independent technical advice panel. Services Australia administers the stoma association claiming and payment process and the registration of new participants in the Scheme.

Stoma-related products subsidised under the Scheme currently include one-piece and two-piece pouching systems, irrigation devices, catheters, hernia support garments, creams and ointments, deodorants, protective films, skin cleansers, powders and pastes.

1.2 SAS Schedule

All products available under the Scheme are listed on the SAS Schedule which specifies the following information for each product:

- Group and Subgroup
- SAS code
- Company product code
- Product name
- Product description
- Pack size in units
- Allowable monthly/annual (if applicable) maximum quantity
- Price per pack
- Price Premium (if applicable).

1.2.1 Groups and Subgroups

Stoma-related products which have comparable features or functions are placed together in a group. Products may be further classified based on their distinct features and placed in subgroups. Groups are identified numerically, with alphabetical suffixes to indicate subgroups.

The Schedule is currently divided into 11 groups and 38 subgroups:

Table 1:Stoma Appliance Scheme (SAS) 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

1.2.2 Benchmark products and prices

Product prices in the SAS Schedule are set by the Department following advice from SPAP and negotiation with sponsors.

The Department has defined a benchmark price for each subgroup in Groups 1 to 7 of the SAS Schedule. This allows new products listed on the SAS Schedule in these subgroups to be priced consistently and transparently in relation to existing products. All new products seeking listing on the SAS Schedule must either be equivalent or superior to a benchmark product of the relevant subgroup in terms of features, safety and clinical effectiveness.

Products listed in Groups 8, 9, 10 and 11 will be reviewed by SPAP to determine the most appropriate benchmarking process.

1.2.3 Price premium products and prices in Groups 1 to 7

Products may be eligible to be listed as price premium products at a higher price than the benchmark price in a subgroup if they are assessed by SPAP as providing improved health outcomes and are cost-effective at the higher price.

The price premium is set by the Department following advice from SPAP and is determined by assessing the improved quality of life and/or survival provided by the product in comparison to a benchmark product. The Premium column in the SAS Schedule specifies the premium applied to the pack price of listed premium products.

1.2.4 Maximum Quantities

The SAS Schedule specifies the maximum number of units of stoma-related products available to participants under the Scheme per month (or annually if relevant). Maximum quantities for each subgroup are set by the Department after consultation with SPAP and are designed to reflect clinically appropriate usage.

Scheme participants can apply for additional supplies of stoma-related products, if required, where their condition cannot be managed with the specified maximum quantity following consultation with a stomal therapy nurse.[1]

1.2.5 The Stoma Product Assessment Panel

The Stoma Product Assessment Panel (SPAP) is an independent technical advice panel appointed by the Department to review applications from sponsors for inclusion of stoma-related products on the SAS Schedule.

The Department established the SPAP in 2002 and restructured it following a 2009-2010 review to improve its independence and ability to assess economic evidence. The SPAP comprises 9 members:

[1] Scheme participants apply to their association for additional supplies – refer to SAS Operational Guidelines for further details

- an independent chair
- clinical and economic experts
- a consumer representative
- non-voting representatives from the Australian Council of Stoma Associations (ACSA) and industry.

The primary role of the SPAP is to consider applications from sponsors for the listing of new products on the SAS Schedule and to make recommendations to the Department regarding those applications.

The Terms of Reference for the SPAP are:

1. Provide advice to the Department on definitions, criteria, and processes for the inclusion of products on the Scheme.
2. Review and assess products considering effectiveness (i.e. effect on health outcomes for participants), quality, ease of use, safety, cost and cost-effectiveness and to provide a recommendation to the Department.
3. Ensure that high quality stoma-related products are contained in the Scheme, and periodically review products and associated pricing as required.
4. Where requested, provide advice to the Department on appropriate structuring of the SAS Schedule, and where appropriate recommend strategies or principles in relation to schedule management.
5. Consider policy issues in relation to the Scheme as directed by the Department.

The SPAP Secretariat provides administrative support to SPAP. Its functions include:

- Managing the receipt of applications to list stoma-related products on the SAS Schedule, including compliance with application administrative requirements
- Maintaining the SAS Schedule and Schedule release arrangements
- Managing the administrative aspects of SPAP meetings and the preparation of Public Summary Documents
- Providing advice regarding policy and administration of the Scheme.

Part 2 – Application Guidelines and Evidence Requirements

This part of the document is to provide guidance to sponsors who wish to submit an application to:

- list a new stoma-related product on the SAS Schedule
- vary a current product listing, or
- delete a current product from the SAS Schedule.

Application forms can be found on the Department's Stoma webpage or can be requested from the SPAP Secretariat at: stoma@health.gov.au or phone: (02) 6289 2308.

2.1 Who can apply

A sponsor of a stoma-related product must meet the following conditions:

- have an Australian Business Number (ABN)
- be able to guarantee supply of the product to eligible stoma associations in Australia at the time of listing.

Products can only be listed on the SAS Schedule if the listing has been initiated by a sponsor who meets the conditions listed above.

2.2 Products eligible to be listed on the Scheme

A product may be considered for listing on the SAS Schedule providing it meets the following conditions:

- The product is registered on the Australian Register of Therapeutic Goods (ARTG) if applicable, and the listing details from a valid ARTG certificate are specified in the application.[2]
- A product can still be assessed if it does not have an ARTG certificate, but it cannot be listed on the SAS Schedule until the details of the certificate are provided and verified by the SPAP Secretariat.
- There is a clinical need for the product in management of a stoma, and evidence of clinical effectiveness for the product.
- The product will be available to be supplied from the date it is listed on the SAS Schedule.

Additional conditions apply to applications for products at the benchmark price and price premium products, as set out below.

[2] This requirement does not apply for products that are excluded from TGA regulation such as adhesive removers and non-medicated skin cleansers.

2.2.1 Products at the Benchmark Price

- The product is no worse than its comparator regarding safety and/or efficacy.
- The product's requested price does not exceed the benchmark price for the relevant subgroup.

2.2.2 Price Premium Products

- The product has been compared to one or more comparators on the SAS Schedule and SPAP considers that the evidence indicates:
  - it is superior in efficacy and/or safety
  - its cost effectiveness relative to its clinical effectiveness
  - where the product cannot be compared to a product currently listed on the SAS Schedule, evidence of its clinical and cost effectiveness is provided.

2.3 Application to List Products

2.3.1 Benchmark Listing and Price Premium Applications

The applicant should consider the type of application and use the relevant form when lodging an application. There are separate application forms for:

- Benchmark Listings in Groups 1 to 7
- Listings in Groups 8 to 11
- Listings for Price Premium products.

Products listed in Groups 8, 9, 10 and 11 will be reviewed by SPAP to determine the most appropriate benchmarking process for these products.

The application form is divided into 7 sections. Information relating to the completion of each section is provided below. Applicants should complete all sections of the application form. Where information is not available, a statement to this effect should be included in the relevant section.

If applying to vary a currently listed product, please refer to **Part 2.4 Application to Vary a Listing**. If applying to delete a currently listed product, please refer to **Part 2.5 Application to Delete a Listing**.

2.3.2 Completing a new application

Section 1 – Applicant Details and Declaration

The applicant must be the sponsor of the stoma-related product in Australia. All contact information should be completed, and the nominated contact officer should be able to assist with any queries about the application at both the time of submission and when the application is considered by SPAP. The person who signs the application declaration must be able to legally bind the applicant.

Section 2 – Product Information

The applicant should provide information about the product and upload an image of the product in the space provided in the application form.

The applicant should indicate which group and subgroup the product is to be listed in. If the product cannot be categorised in an existing group and subgroup (e.g. because the product is new technology, is satisfying a previously unmet clinical need, or there is uncertainty), the applicant should complete the Price Premium Form and fully describe the features or technology which differentiate the product.

The product name is the name under which the product is or will be supplied in Australia. This name should also appear on any product packaging. The quantity per pack should also be provided.

Details of a valid ARTG Certificate of Inclusion for the product must be supplied if applicable, on the SAS. This includes the name of the sponsor, the ARTG ID number and a list of specific indications and/or conditions of inclusion of the product on the ARTG. A product can still be assessed if it does not have an ARTG certificate, but it cannot be listed on the SAS Schedule until the details of the certificate are provided and verified by the SPAP Secretariat. The name of the applicant should be the same as the sponsor's name that appears on the ARTG certificate.

It is important to include all the product's features and relevant information. Do not include any promotional descriptions to describe the product's features or technology.

If the application is to list a product range with multiple variants, use the Microsoft Excel Product Features Table to add additional variants within the same product range to an 'Application to list a product – Benchmark Groups 1 to 7' or 'Application to list a product - Price Premium Products'. Only fill out the fields in the table for features that are relevant to the product.

A comparator must be nominated from the SAS Schedule, including its group and subgroup. The comparator should be the product most likely to experience a change in utilisation if the product in the application is listed on the SAS Schedule.

Section 3 – Clinical Assessment Information

The purpose of this section is to obtain all relevant clinical information about the product to enable it to be fully assessed against to the appropriate comparator. Information provided under this section will be used to assess the product's clinical effectiveness and safety.

Information may include, but is not limited to:

- information concerning the clinical need for the product
- evidence of the clinical and safety benefits of the product over the specified comparator or other relevant products
- clinical opinion concerning the product
- evidence from literature searches

If information on patient preferences is provided, it should be supported by objective data as described at 3.2.3.

Additional information for Groups 8 to 11 and Price Premium applications

Clinical efficacy

SPAP will consider the strength and quality of evidence and its relevance to Australian practice and conditions when assessing an application. It is important to consider the evidence provided particularly relating to leakage and skin condition where the product is in contact with the stoma or skin.

For applications requesting a price premium, the SPAP will place the highest value on systematic reviews of high-quality randomised trials (level 1), noting some randomised trials are poorly organised may provide less information than a non-randomised trial.

If a study is provided for a product that is not currently funded in Australia, it is important to consider whether the product is adequately described in the study and accompanying submission and can be compared to a product or products with similar features.

Safety

If possible, a summary of the adverse events related to both the product for which listing is sought and the comparator nominated in Section 2 (if applicable) should be provided. Details of adverse events should include the nature, frequency and outcome of any event.

Literature Search

A literature search should be conducted for price premium requests to identify evidence supporting the clinical nature, clinical effectiveness, safety, and cost effectiveness of the product. Results of both published and unpublished (in house) studies should be provided in the application.

A description of the search strategy used to retrieve relevant studies, as well as the specific databases searched and dates of the searches should be included. Where a literature search has not provided any additional evidence, the applicant should indicate this by marking the relevant check box.

Section 4 – Economic Assessment Information

The purpose of this section is to obtain relevant economic information, if available, about the product, to allow the cost and cost effectiveness of the product to be assessed in relation to the nominated comparator or other relevant products. This will enable SPAP to determine whether the product is likely to represent value in terms of expenditure on healthcare in Australia.

Benchmark Listing

Applications for benchmark listing will be assessed on a cost minimisation basis.

Price Premium

Applicants requesting a price premium should provide evidence demonstrating the product offers an improved health outcome over the appropriate benchmark comparator, and that the higher cost can be justified.

SPAP recognises there are different methods for assessing costs and outcomes in health economic analyses. The most widely used methods are cost-effectiveness, cost utility and cost benefit analyses.

Section 5 – Financial Assessment Information

The purpose of this section is to seek information about the proposed price, the proposed monthly (or annual) maximum quantity and potential utilisation of the product.

Information about the predicted change in utilisation of other products resulting from listing the new product and the corresponding cost offsets should also be submitted. Predicted utilisation of the product under the Scheme and corresponding costs for the first 4 full years should be specified. Epidemiological data (incidence and prevalence of the condition for which the product will be used) should be included in this section. Data references for derived estimates are required.

All pricing information and cost calculations should be in Australian dollars.

Note: Where SPAP has rejected an application to list a price premium product on the basis of price, the Department may negotiate with the applicant to list the product in the relevant subgroup at the benchmark price provided it meets the requirements for a benchmark product listing.

Section 6 – Additional Information

The purpose of this section is to allow any further information not included in previous sections and relevant to the assessment of the product to be provided. Additional information may include reports from international regulatory authorities and health technology assessment committees, unpublished studies, and manufacturer studies.

Confidential Material

The applicant should identify which parts of the information in the application are considered confidential material and detail the reasons why. Confidential material will not be included in any public documentation released by the Department where there is sufficient justification for the information to be excluded. However, all information supplied in an application will be provided to SPAP for consideration.

The details provided by the applicant under this section will be used by SPAP and the Department to determine the information which can be released as part of the publication of SPAP meeting summary outcomes and, if the product is approved for listing, the information that will be included to describe the product in the SAS Schedule.

Section 7 – Supporting Documentation

The purpose of this section is for the applicant to list the supporting documents that will be submitted with the application, noting which section of the application they support.

Further information about how SPAP will assess applications can be found in Part 3 – Assessment Guidelines.

2.4 Application to Vary a Listing

A sponsor may apply to vary a product which is currently listed on the SAS Schedule. Sponsors seeking to vary a product listing should use the *Application to Vary a Listing* form.

Variations are generally processed by the SPAP Secretariat. However, if a variation will affect a product's classification, pricing, maximum quantity or composition (in certain circumstances), the variation will be assessed by SPAP and the sponsor seeking the variation should apply using the application form for new products (see above). SAS codes can only be varied by the SPAP Secretariat.

2.4.1 Completing the Application to Vary a Listing form

Sponsors wishing to vary a currently listed product should complete an *Application to Vary a Listing* form.

The *Application to Vary a Listing* form includes 5 sections. Information relating to the completion of each section is below.

Section 1 – Applicant Details and Declaration

The Applicant must be the sponsor of the stoma-related product in Australia. All contact information should be completed, and the nominated contact officer should be able to assist with any queries.

Section 2 – Product Information

The purpose of this section is to establish which product/s are to be varied on the SAS Schedule. The product's SAS code, product code, group and subgroup should be specified. Use a separate application for products listed under each individual SAS code.

Section 3 – Type of Variation

The purpose of this section is to establish the nature of the variation being sought. Only complete the relevant table/s for the type of variation being sought through the application. Examples of the type of variations that can be included in this section are variations to a company code, sponsor name, product description or name, or pack size.

Section 4 – Additional information

The purpose of this section is to allow any further information not included in previous sections and relevant to the variation of the product/s to be provided.

Section 5 – Supporting Documentation

The purpose of this section is for the applicant to list the supporting documents (if any) that will be submitted with the application, noting which section of the application they support.

2.5 Application to Delete a Listing

A sponsor should apply to have a product deleted from the SAS Schedule if that product can no longer be distributed in Australia. Where possible, a period of notice of not less than

6 months should be given to allow users of the product to seek a suitable alternative and to enable stoma associations to manage their stock levels.

It is important to provide as much information as possible, including the steps that will be taken to inform associations and participants in the Scheme about the deletion. Deletions are generally processed by the SPAP Secretariat.

A product may be deleted from the SAS Schedule if there has been no use of that product under the Scheme for a period of 24 months. SPAP may also recommend deleting a product from the SAS Schedule (e.g. for clinical or efficacy reasons). If so, the sponsor will be notified of the intended deletion and given 6 months' notice of such intention.

2.5.1 Completing the Application to Delete a Listing form

The *Application to Delete a Listing* form includes 3 sections. Information relating to the completion of each section is below.

Section 1 – Applicant Details and Declaration

The Applicant must be the sponsor of the stoma-related product in Australia. All contact information should be completed, and the nominated contact officer should be able to assist with any queries.

Section 2 – Product Information

The purpose of this section is to establish which product is to be deleted from the SAS Schedule. The product's SAS code, product code, group and subgroup should be specified. Use a separate application for products listed under each individual SAS code.

Section 3 – Additional information

The purpose of this section is to allow any further information not included in previous sections and relevant to the deletion of the product to be provided.

If the product is to be deleted earlier than 6 months from the application date, an explanation should be provided in this section. Sponsors may nominate a substitute product in this section, noting that the Department does not include suggested alternative products with its release of the SAS Schedule. This information will be provided to SPAP at its next meeting.

2.6 Lodging an application

2.6.1 When to submit an application

The SPAP Secretariat manages application lodgements. Applications should be completed using the electronic forms located at the SAS Resources webpage. Forms can also be requested by contacting the Secretariat.

A checklist is provided at the end of each Application Form to ensure applicants have included all relevant and requested information.

Applications can be submitted to the SPAP Secretariat at any time throughout the year. The Secretariat will process each application once received and arrange for the application to be

considered at the next SPAP meeting. Applications are assessed by SPAP twice per year. The closing date for applications is usually at least 6 weeks prior to the SPAP meeting date.

Current application timetable details can be found on the Department's Stoma webpage.

SPAP will consider all applications to list products (benchmark and price premium) and applications to vary products currently listed on the SAS Schedule where the variation will affect a product's classification, pricing, maximum quantity or composition. Administrative variations and deletions will usually be processed by the SPAP Secretariat.

2.6.2 Lodgement

Applicants must provide a signed electronic version of the application and all supporting information via email. The completed application and all relevant information should be emailed to the SPAP Secretariat at stoma@health.gov.au. Applicants should complete all sections of the relevant application form. Incomplete applications will be returned to the applicant.

For new products, applicants should provide 3 samples. The product samples for new listing applications should be sent via post to the SPAP Secretariat:

Stoma Product Assessment Panel (SPAP) Secretariat
Department of Health
PO Box 9848
CANBERRA ACT 2601

If more than one application is being submitted, please ensure that the product samples are clearly labelled and separated.

Any questions about the lodgement process should be directed to the SPAP Secretariat via email: stoma@health.gov.au or phone: (02) 6289 2308.

Part 3 – Assessment Guidelines

3.1 Introduction

This part of the Guidelines provides information to applicants about the process used to assess applications to list new stoma-related products on the SAS Schedule, including how clinical and economic evidence will be assessed by SPAP and the process following a SPAP recommendation.

Applications are examined by the SPAP Secretariat to ensure they comply with administrative requirements.

When an application is received by the Department, it is logged by the SPAP Secretariat and an email confirmation is sent to the applicant within 2 business days. Incomplete applications will be returned to the applicant. The Secretariat will conduct a preliminary examination of the application to ensure that it contains all information required to support an application for listing. The Secretariat will contact the applicant to clarify or seek additional information if required.

3.2 Assessment by SPAP

3.2.1 Assessment process

SPAP provides advice to the Department concerning which stoma-related products are suitable for listing on the SAS Schedule. SPAP must have regard to comparative clinical function and effectiveness, comparative cost effectiveness and comparative safety.

While not directly part of the Australian Government's Health Technology Assessment (HTA) system, SPAP endeavours to ensure that it undertakes the Scheme application assessment process in a way that is:

- sustainable
- transparent, accountable and independent
- consultative and reflective of Australian community values
- administratively efficient and cost-effective
- flexible and fit for purpose
- informed by robust and relevant evidence.

To list a new product at the benchmark price

For applications requesting a product be listed at the benchmark price for a given Group/Sub-Group, evidence must be presented that the product is no worse than its comparator regarding both safety and efficacy.

To list a price premium product

For a product to be granted a price premium over a currently listed comparator product, evidence must be provided to the SPAP that demonstrates:

- an incremental clinical benefit is provided to patients
- the incremental costs are justified by demonstrating that the product is of acceptable cost-effectiveness at the price requested.

3.2.2 Assessment questions

The SPAP will assess the application, considering the:

- features and proposed use of the product
- relevant background to the application
- appropriateness of the product
- any proposed restrictions or maximum quantities
- clinical need for the product and its placement in the clinical pathway
- appropriateness of the comparator
- clinical evidence
- economic and financial analysis
- recommendations for inclusion and price on the Schedule.

3.2.3 Assessing evidence

As noted in Part 2.3 – Application to List Products, there is a minimum level of evidence required, and it is acknowledged that the level of evidence available may vary among applications. SPAP will consider the relevance and propriety of the evidence submitted including:

- Has an appropriate approach been used to select studies for presentation in the application (i.e., is there any risk that there is selection bias in the presentation of studies)?
- What is the quality of the studies (i.e., what is the likelihood the results of the studies have been affected by bias during their conduct)?
- Are the results of the studies presented consistent and are they consistent with the results of studies that may have been excluded from presentation in the application?
- Is there any reason why results of the studies may not be generalised to the Australian setting?
- Does the trial design minimise bias, e.g., carry-over effects? For studies involving the measure of skin integrity, the minimum duration should be no less than 4 weeks for each phase of the study.
- Are the endpoints measured relevant to patients e.g., leakage, skin integrity, ballooning?

- Are the endpoints surrogate outcomes, and if so, have they been validated? e.g. air flow rates through filters on ostomy bags should be correlated with the incidence of ballooning and/or odour.
- If standardised measures are used e.g., for skin integrity, what is the inter and intra-rater variability? How was this tested and how may this influence the results of the studies?
- Are patient-preference studies included in the application? How were these studies conducted to minimise confounding of the results? Is there a correlation between differences in patient relevant outcomes and expressed patient preferences? If not, why not?
- Is the data on comparative safety and effectiveness the result of head-to-head trials with the comparator or via indirect analyses?

SPAP will refer to the National Health and Medical Research Council (NHMRC)'s Hierarchy of Evidence when assessing the quality of evidence presented in applications[3].

Product information or statements and testimonials from sponsors or clinicians will not be sufficient to demonstrate clinical effectiveness or superiority. If the SPAP does not consider the evidence provided is sufficient to support a positive recommendation for the application, the SPAP may defer the application until sufficient evidence is provided.

3.3 SPAP Recommendations

Following consideration of an application to list a new product on the SAS Schedule, SPAP will decide whether to recommend the product for listing. At the conclusion of each SPAP meeting, SPAP's recommendations are provided to sponsors for their respective applications and will be provided to the Department delegate.

A recommendation will include:

- whether the product should be listed on the SAS Schedule
- an explanation of SPAP recommendations.

If SPAP recommends that the product should be considered for listing on the SAS Schedule, it will also provide the following information:

- Monthly (or annual) maximum quantity for the product
- The price at which the product should be listed
- Any usage restrictions, if relevant.

The SPAP determines if products on the SAS Schedule will be subject to restrictions. Where a product is subject to a restriction, the restriction group will be identified as part of the product description on the SAS Schedule. Restriction definitions are below.

[3] The NHMRC Evidence Hierarchy is available on NHMRC webpage

Restriction Group	Definition
R1	Requires STN, Nurse Practitioner, Registered Nurse or Registered Medical Professional authorisation.
R2	No authority for an increase in the yearly allocation can be granted.
R3	Strict Usage Restriction – Requires STN, Nurse Practitioner, Registered Nurse or Registered Medical Professional authorisation including clinical justification.
R4	Strict Usage Restriction – Requires Colorectal or General Surgeon authorisation.

Sponsors can request a meeting with the SPAP Secretariat to discuss the outcomes of the SPAP meeting.

Where SPAP has rejected an application to list a price premium product on the basis of price, the Department may negotiate with the applicant to list the product in the relevant subgroup at the benchmark price provided that SPAP has confirmed:

- the product is no worse than its comparator regarding safety and efficacy; and
- it does not intend to expand the subgroup's benchmark product definition.

The Secretariat prepares Public Summary Documents (PSDs) which are ratified by the SPAP and sent to sponsors for comment. The ratified PSDs with sponsor comments are published on the Department's website, usually within 2 months after the SPAP meeting.

3.4 Decision Review

All unsuccessful applications can be resubmitted to SPAP for consideration at a subsequent SPAP meeting providing they include additional information which addresses the SPAP concerns outlined in its initial advice.

Part 4 – Product listings

The Department delegate will consider SPAP recommendations.

Where a positive recommendation for the listing of a benchmark or price premium product has been given by SPAP, irrespective of its fiscal impact, the Department will advise the Department of Finance and the Minister for Health and Aged Care (or delegate) and seek approval to schedule a listing submission to be considered by Government. This approval process may take up to 4 months and is dependent on competing priorities.

If products are approved for listing by Government, the Department will facilitate publishing the SAS Schedule on the date determined by Government. Once a listing is approved, sponsors are notified of the agreement by Government and the effective date of change and asked to confirm the changes to their products are correct. The updated Schedule is circulated at least one month prior to the new effective date to stoma associations (through ACSA) and Services Australia to allow all organisations to prepare for the changes.

4.1 Listing Process and timing for Schedule Updates to the Stoma Appliance Scheme

1. Applications and product samples accepted up to 6 weeks prior to scheduled SPAP meeting date. Applications are considered at SPAP meetings which are usually held twice a year.
2. SPAP meeting. SPAP recommends whether products should be listed/varied/deleted on the Schedule, or defers its recommendations to be considered at a later meeting.
3. Meeting outcomes are sent to sponsors approximately 2 weeks following the meeting.
4. Public Summary Documents (PSDs) are prepared and ratified by SPAP (approximately 4 to 6 weeks after the meeting).
5. Sponsors are given 1 to 2 weeks to review and comment on PSDs.
6. PSDs published on the Department's webpage approximately 6 to 8 weeks following the SPAP meeting.
7. SPAP recommendations for proposed listings, variations, or deletions on the SAS Schedule and a proposed listing date are sent to the Department of Finance and Government for approval. Note: This process can take between 2 to 4 months and is dependent on competing priorities of Government.
8. Sponsors are advised of the approved listing date and sent reports with the proposed listings, variations, or deletions on the SAS Schedule for their respective products to review. Sponsors are given a week to review the reports and make any comments. It is important that these reports are reviewed carefully and any errors reported to the Department as all details of the reports will be reflected in the SAS Schedule.
9. The SAS Schedule is sent to stakeholders including Services Australia, ACSA and the Department's web team 4 weeks prior to the listing date to prepare for the Schedule update.
10. The SAS Schedule is updated.

Glossary

The following terms and abbreviations have the meanings indicated:

Term	Definition
ACSA	Australian Council of Stoma Associations
Adverse Event	Any unfavourable or unintended change in health or side effect that occurs while a participant is receiving treatment for a condition or using a specific stoma-related product for that condition
ARTG	Australian Register of Therapeutic Goods as established under the *Therapeutic Goods Act 1989*
ARTG Certificate of Inclusion	Certificate from the TGA eBS system following a product's inclusion on the ARTG
Benchmark Product	The notional stoma-related product within each subgroup that comprises a specified set of features, as updated from time to time, which represents the minimum standard product which would be used by a participant in the Scheme who has a need for a product in the subgroup
Benchmark Price or Benchmark Product Price	The price of the benchmark product in a subgroup. Derived by calculating the sum of the base product price plus the specified cost of each key feature of the benchmark product additional to the base product's set of key features. For a product to receive the benchmark price that applies for a subgroup, the product must include all the specified key features
Clinical effectiveness	The measurement of the improvement of health outcomes attributable to a stoma-related product
Comparative effectiveness	The measurement of the clinical and economic benefits of a stoma-related product compared to an alternative product
Comparator	A stoma-related product nominated by an applicant as the product with similar features and benefits most likely to be replaced, or experience a decrease in utilisation, if the applicant's product is listed
Confidential material	Information which may be withheld from the public or unauthorised persons because disclosure would cause a foreseeable harm to the organisation which supplied the information

Term	Definition
Cost-effectiveness	The measurement of the incremental cost relative to the incremental health outcomes achieved by a stoma-related product compared to the alternative product that is most likely to be replaced
Cost-minimisation analysis	Analysis which considers whether the proposed intervention is demonstrated to provide a health outcome which is at least no worse than another intervention at the same or a lower price
Department	Department of Health and Aged Care
Departmental delegate	The relevant Departmental Officer holding delegation to make formal decisions in relation to the Scheme
Feature	A specified component of a stoma-related product
Finance	The Department of Finance
Group	A collection of stoma-related products which comprise similar features listed together within the SAS Schedule
Health outcome	A change (or lack of change) in a person's health status resulting from utilisation of the stoma-related product of interest compared to health status when using the comparator. Health status may be assessed when using disease-specific measures, health-related quality of life measures; measurement of survival; or a combination of these measures
HTA	Health Technology Assessment
Manufacturer Code	The code assigned to distinguish a sponsor by the Department, as specified in the SAS Schedule
Maximum quantity	The number of units of a product which can be provided to a participant in the Scheme per month (or annually where relevant)
Participant	A member of a stoma association who is eligible to receive stoma-related products through the Scheme
Price difference	The difference in the price paid between the price of the benchmark product and the premium price product in each subgroup

Term	Definition
Price Premium	The incremental price that has been justified for a key feature that provides improved health outcomes, additional to those provided by the benchmark product
Price Premium Product	A stoma-related product within a subgroup, which has one or more key features for which a price premium has been approved
Product	A stoma-related product used in the management of a stoma and/or fistula
Related feature	A feature, as determined by SPAP, which must be part of a benchmark product
Restriction	A limitation on when a product on the Scheme can be used, included as part of the product description on the SAS Schedule
SAS	Stoma Appliance Scheme
SAS Code	The 5- or 6-digit alphanumerical code given to stoma-related product when listed on the SAS Schedule which is used to identify the product for Services Australia for Medicare claiming purposes. The SAS Code is also referred to as the PBS item code.
SAS Schedule	The list of stoma-related products which can be accessed under the Scheme and their associated SAS codes, sponsor codes, product descriptions, prices and maximum quantities. The SAS Schedule also specifies whether a stoma-related product is a benchmark product or a price premium product
Scheme	Stoma Appliance Scheme
Services Australia	Services Australia
SPAP	Stoma Product Assessment Panel
Sponsor	The manufacturer or distributor of stoma-related products in Australia which are listed or may be listed on the SAS Schedule
Stoma	For the purposes of the Scheme, a stoma is 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 faeces from the body where the person does not have normal bowel or bladder functions

Term	Definition
Stoma-related product	A therapeutic device, appliance, aid or product which is used in the management of a stoma or fistula.
Subgroup	A collection of stoma-related products with similar key features which form part of a group in the SAS Schedule
TGA	Therapeutic Goods Administration
Variant	A form of a related feature