Australian Government
Department of Health

Stoma Appliance Scheme - Operational Guidelines

Contents

1. Overview

The purpose of this document is to describe the practices and procedures that must be followed by participating stoma associations who provide stoma-related products to their members under the Australian Government's subsidised Stoma Appliance Scheme (SAS).

This document includes requirements relating to:

- membership
- supply of stoma-related products
- reporting
- financial obligations and
- claims processing and payments.

1.1 *National Health Act 1953* (NHA)

The Stoma Appliance Scheme Operational Guidelines form part of the arrangements made by the Minister (or delegate) under Section 9A(1)(a) of the NHA.

Provision of medical and surgical aids and appliances etc. by the Commonwealth

(1) The Minister may, on behalf of the Commonwealth, arrange for:
  (a) the supply by the Commonwealth of such medical or surgical aids, equipment or appliances as are prescribed to persons who require them;
  (b) the making of any modifications to a building, vehicle or equipment that are necessary for the treatment or rehabilitation of a sick or disabled person.

(2) Subject to the provisions of an arrangement made under subsection 9C(1), a hearing aid, or any other medical or surgical aid, equipment or appliance of a kind prescribed for the purposes of this subsection, that is supplied under this section remains the property of the Commonwealth notwithstanding any purported disposition or pledging of the aid, equipment or appliance by any person.

(3) The Minister may impose such conditions as the Minister thinks fit on the use or possession of aids, equipment or appliances supplied, or to be supplied, under subsection (1).

(4) The regulations may make provision with respect to the supply of aids, equipment or appliances, or the making of modifications, under subsection (1), including provision for offences with respect to the use or possession of aids, equipment or appliances so supplied.

1.2 Definitions

ACSA	Australian Council of Stoma Associations
Stoma association	Associations distributing stoma-related products
The Department	Australian Government - Department of Health
Services Australia	Australian Government – Services Australia
Member/Ostomate	Eligible person who receives products under the SAS
SAS	Stoma Appliance Scheme
SPAP	Stoma Product Assessment Panel
STN	Stomal Therapy Nurse
GST	Goods and Services Tax
HPOS	Health Professional Online Services portal
RHCA	Reciprocal Health Care Agreement
Purpose	Describes the use of a product listed on the SAS Schedule
Remote	As defined by the Rural, Remote and Metropolitan Area (RRMA) classification. For the purposes of the SAS, considered to be Rural zone RRMA 3 to 5 and Remote zone RRMA 6-7.

2. Roles and responsibilities

2.1 Department of Health

The Australian Government through the Department of Health (the Department) is responsible for the program. The Department oversights and supports the Stoma Product Assessment Panel (SPAP), monitors program access and compliance and approves (new) stoma associations. The Department works closely with Services Australia and liaises with ACSA on program issues.

2.2 Services Australia

Services Australia administers SAS benefits on behalf of the Department. Services Australia manages the processing and payment of claims lodged for SAS products (including the provision of payment statements) and provides data on SAS activity to the Department. Services Australia also works with the Department and liaises with ACSA to ensure payment integrity.

2.3 The Australian Council of Stoma Associations (ACSA)

ACSA represents, at a national level, all stoma associations across Australia. ACSA has primary responsibility for the distribution of stoma-related products listed on the SAS Schedule, by its member stoma associations. ACSA is responsible for periodically monitoring compliance by stoma associations with the Operational Guidelines, and for responding to requests from the Department and Services Australia as communicated from time to time. ACSA also liaises with the Department and suppliers, and coordinates support services for people with a stoma throughout Australia.

2.4 Stoma associations

Stoma associations are not-for-profit organisations which distribute stoma-related products through the SAS. Stoma Associations must be members of ACSA and must follow requests made by the Department or Services Australia through ACSA. Stoma associations order SAS products for eligible ostomates, provide information and support their members. Stoma associations are responsible for ensuring all orders and claims meet schedule and payment integrity requirements under the SAS.

Stoma associations are required to provide representatives of ACSA, the Department and Services Australia with open and transparent access to any documentation and records related to the distribution of stoma-related products listed on the SAS Schedule when requested. Such a request will be in writing and will be for monitoring the stoma association's compliance with the Operational Guidelines and any other purpose related to SAS administration. Open and transparent access may involve viewing documentation and records within the operating premises of the stoma association.

2.5 SAS participants (ostomates)

A SAS participant is an eligible person (clause 4.1.1) who has submitted an application for registration to the Stoma Appliance Scheme. A SAS participant must be a member of an approved stoma association of their choice and should be familiar with the policies and procedures of that association with regard to SAS ordering policies and timeframes. A SAS participant is also required to pay any costs associated with obtaining stoma products that are not met by the Stoma Appliance Scheme (e.g. delivery of products). A SAS participant must only use products supplied through the SAS for their own personal use.

3. Eligibility

3.1 Requirements of Stoma Associations

All enquiries on the establishment of a new stoma association should be directed to the Department through ACSA.

New and existing stoma associations should:

- be a member of ACSA;
- demonstrate knowledge of, and the ability to administer, the SAS;
- be prepared to establish a separate financial accountability for the operation of the SAS where the stoma association is being sponsored by an existing organisation;
- be able to demonstrate that they have a reasonable membership base which provides for financial viability (as described below);
- operate a premises with adequate space to ensure timely ordering, packing and distribution of orders to ostomates;
- once approved by the Department, seek immediate approval for electronic claiming by Services Australia;
- be able to electronically order stoma-related products, and submit electronic claims in a format/manner approved by Services Australia being HPOS Version 2 (from 2020 and any later versions thereafter);
- provide ostomate support, through ostomy support programs (for example);
- be able to demonstrate financial viability in respect of:
    - operating revenue;
    - the provision of suitable premises as described above;
    - acquisition and maintenance of a computer based ordering and claims program;
    - funding inventory;
    - funding staffing requirements and/or volunteer assistance;
- comply with the guidelines (as in place from time to time) and;
- meet payment integrity requirements by Services Australia and the Department.

3.2 Premises and supply of stoma-related products

The premises of a stoma association may be located within a hospital complex or a private building.

3.2.1 Facility requirements

Premises should allow adequate space to enable timely ordering, packing and distribution of orders to ostomates.

3.2.2 Premises located in a hospital

Where a stoma association operates within a hospital complex this needs to be separate to the hospital's administration or services. Specifically, stoma associations must not provide SAS products to in-patients of the hospital or purchase stoma-related products through the hospital.

A working relationship can exist with the local hospital, for example, if there is a Stomal Therapy Nurse (STN) in the hospital. Arrangements for members to have access to this service can be made in a non-inpatient setting.

3.3 Dispute resolution

Stoma associations that experience operational problems in relation to the SAS must first refer the matter to ACSA for advice or assistance. If ACSA cannot resolve the matter they will seek assistance from either the Department or Services Australia. However, issues relating to the submission, processing and payment of individual claims should be referred directly to Services Australia, unless they are of a general nature in which case they should first be discussed with ACSA.

4. Stoma Appliance Scheme membership

4.1 Eligibility

4.1.1 General requirements

To access stoma related products under the SAS, a person must:

- have a temporary or permanent artificial body opening (created surgically or otherwise) which facilitates the removal of urine and/or products of the gastrointestinal tract where the person does not have normal gastrointestinal tract or bladder functions, and provide evidence, consisting of a certificate from a registered medical practitioner or STN in an approved form (PB049);
- be an eligible person within the meaning of the *Health Insurance Act 1973*. An eligible person means an Australian resident or an eligible overseas resident;
- reside in Australia in order to receive stoma-related products under the SAS (products will not be supplied under the Scheme if a period of more than six months is spent overseas); and
- have one of the following forms of identifying information which must be provided as part of a claim for payment for the supply of a product:
    - a current Medicare or Department of Veterans' Affairs entitlement number;
    - a current Australian Reciprocal Medicare Card number (if the person is a resident of a country that has signed a Reciprocal Health Care Agreement with Australia); or
    - a current passport number if the person is a resident of New Zealand or the Republic of Ireland.

4.1.2 Reciprocal Healthcare Agreements

Visitors to Australia who are eligible to receive benefits under a Reciprocal Health Care Agreement (RHCA) can access stoma-related products under the SAS for the period of their stay in Australia by virtue of subsection 7(2) of the *Health Insurance Act 1973*.

There is no legislative basis for visitors to Australia to be excluded from receiving products through programs subsidised under Section 9A of the *National Health Act 1953* (unless the Guidelines for the program specifically state the exclusion). Therefore, access to benefits under the RHCAs should be honoured by the SAS.

The RHCAs do not exclude pre-existing conditions from eligibility; the only exclusion is 'medical tourism', where someone enters Australia for the express purpose of receiving treatment. It is at the discretion of the stoma association as to whether the visitor is required to become a temporary association member.

4.1.3 Norfolk Island members

From 1 July 2016 mainland Australian taxation, social security, immigration, biosecurity, customs and health arrangements, including Medicare and the Pharmaceutical Benefits Scheme, were extended to Norfolk Island. Ostomates residing in Norfolk Island must still satisfy the definition of an 'SAS participant' as stated in clause 2.5 and eligibility requirements as stated in clause 4.1.1.

4.1.4 Members incarcerated

All enquiries relating to incarcerated persons' access to stoma-related products should be referred to the Department for consideration. The Department will provide any decisions relating to supply, after consideration, via email within five business days.

5. Association fees

5.1 Stoma Appliance Scheme access fee

The access fee is set by each stoma association and is payable to the stoma association where the member (usually) obtains their stoma-related products. The fee shall be payable once per financial year to the association where the member usually obtains their stoma-related products. The fee is compulsory but stoma associations shall make provision for the fee to be paid by instalment in the case of financial hardship. The fee can also be pro-rated where a member joins the association part way through a year.

5.2 Stoma association membership fee

Stoma associations may charge an additional membership fee at the stoma association's discretion. This fee cannot be for services covered by the access fee. Stoma associations are required to advise members that the membership fee is separate to the access fee and that the membership fee is determined by the stoma association. A member who is not able to pay the additional stoma association service fee because of financial hardship may apply to the stoma association to have the additional fee paid in instalments or waived. The fee can also be pro-rated where a member joins the association part way through a year.

6. Reporting requirements for stoma associations

6.1 Reporting to ACSA

Stoma associations are required to provide ACSA with:

- monthly new membership numbers and statistics;
- annual membership numbers and statistics;
- details of members accessing the SAS;
- yearly financial statements; and
- any other information related to SAS activities as requested.

ACSA is required to provide the above information to the Department on an annual basis, or as requested.

6.2 Reporting to Services Australia

Any change that may affect the day-to-day operation of the payment and processing procedures, in particular any changes to association name, banking details, authorised persons, mailing address and location of premises, must be reported as soon as possible to the Department and Services Australia.

6.3 Reporting to the Department

Any information or data which the Department or Services Australia requests from ACSA or any stoma association must be provided in a timely manner.

7. Supply of stoma-related products

7.1 The SAS Schedule

The SAS Schedule is a list of stoma-related products that are able to be accessed under the SAS. Participating stoma associations are eligible to receive payments for the supply of stoma-related products listed in the SAS Schedule, according to these Operational Guidelines.

The SAS Schedule contains for each product a description, SAS and company product codes, pack size, maximum issue and lists the maximum price that suppliers can charge for a product on the SAS. If a stoma association pays less than the maximum price for an item, Services Australia should be informed of this when claiming. Updates to the SAS Schedule will be distributed to all stakeholders a month prior to commencement.

Certain products on the SAS Schedule are 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 provided below.

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

7.2 Dual or multiple stomas

The following procedures have been implemented for people who have more than one stoma and require additional stoma-related products:

- Issue the first number from the membership numbers allocated to the stoma association by Services Australia for members with a single stoma;
- A second group of entitlement cards is available to each stoma association for use by members who have dual or multiple stomas (number to be as provided by Services Australia). These cards are to be issued by the stoma association to members for their second and subsequent stomas in a similar manner to the initial card issue;
- A copy of the dual stoma application form must be sent to Services Australia endorsed ‘dual stoma’ and indicate the membership number allocated by the stoma association;
- The member, when obtaining stoma-related products, must use one number for normal requirements and the second for additional supplies; and
- Where the second stoma occurs sometime after the first, a second application form must be submitted to Services Australia showing details of the original application and the number allocated and marked ‘dual stoma’.

7.3 Supply limits

7.3.1 Ordering stoma-related products from more than one group listed on the schedule

When supplies are requested from two or more different sub-groups listed on the schedule, but for which the products serve the same purpose, the maximum amount supplied from each group must be reduced accordingly (for example, if the products are supplied equally from two sub-groups then the maximum quantity for each sub-group should be reduced by 50%).

7.3.2 Subsequent requests for stoma-related products

If a member has not ordered or has not been supplied under a one or two-month ordering cycle, they are not entitled to add that supply of stoma-related products to any subsequent claim.

7.3.3 Maximum quantities

Stoma-related products must be supplied within the limits described in the SAS Schedule, except in the following circumstances.

Two- month ordering cycle

A two-month ordering cycle is available to members who have had their stoma for six months or longer. The ordering cycle will be suspended for members during any period when the stoma-related products they order are subject to change or review. A two-month ordering cycle must be indicated when submitting a claim for payment.

Clinical reasons

Where clinical reasons require an ostomate to be supplied with more than twice the standard maximum allowance of products as defined in the SAS Schedule, a clinical justification letter authorising the additional quantities stating the reason for the additional products above the supply limit must be issued and signed by the member's medical practitioner or STN and attached to the Application for Additional Stoma Supplies (Services Australia form PB050).

Where clinical reasons require an ostomate to be supplied with more than four times the supply limit as defined in the SAS Schedule, the stoma association must forward the Application for Additional Supplies Authority (PB050) and clinical justification letter to the Department requesting approval of the additional supplies.

All clinical justification letters provided for additional supplies must include the member's name and address along with the member's SAS entitlement number and the relevant form of identifying information (clause 4.1.1). The clinical justification letters are only valid if they are issued by a medical practitioner or an STN. Each clinical justification letter is valid for a period of up to six months from the date nominated.

Holidays

Members are entitled to have up to six months' supply if travelling overseas. Members requiring more than two months' supply of products will need to supply associations with proof of travel, such as travel documents and ensure the provision of a completed PB050 form.

Stoma-related products for members living or working in remote locations

Members working and living in remote locations (see clause 1.1, Definitions) are eligible for approval for additional stoma supplies. The member must be under the continuing care of a medical professional (either a registered medical practitioner or a STN) and have regular and ongoing reviews. The original Services Australia form PB050 must be returned to the stoma association and will be considered incomplete if not signed and dated by a recognised medical professional or STN. The Department will consider each application on a case-by-case basis.

Norfolk Island ostomates

Norfolk Island ostomates are covered by special arrangements allowing them to receive six months' supply of stoma products at one time.

NOTE: Evidence of these circumstances must be provided with a claim for payment for payment to be eligible in accordance with the requirements of the PB050 form.

7.4 Stoma-related products monitoring and availability

7.4.1 Unavailability of products

In the event of unavailability of a product, an alternative product may be supplied where an order has been placed by the member for the alternative product. Members should be advised to seek advice from an STN or their medical practitioner should this occur, prior to selecting an alternative product.

7.5 Receipt of stoma-related products

Stoma associations must hold records to demonstrate that they are reasonably satisfied that all products for which they are submitting claims for to Services Australia for payment, have been provided to an ostomate.

Where an ostomate does not pick-up a product which has been ordered and claimed for, the stoma association may transfer the product to another ostomate without further claims for payment. Products must not be on-sold for profit.

8. Pricing

8.1 Pricing arrangements

Prices for the supply of approved stoma-related products are negotiated directly by the Department with the relevant supplier. GST is not payable on any item listed on the SAS Schedule. GST is only payable on the 2.75% handling fee.

Stoma associations are responsible for the purchase of stoma related products to distribute to their members. They are reimbursed on the listing price in the SAS Schedule, plus a 2.75% handling fee.

9. Services Australia claims processing and payments

9.1 Preparation of a claim for payment

A stoma association is responsible for ensuring a claim for payment of the supply of stoma-related products accurately reflects the products supplied to its members. It must also satisfy the claiming requirements as stipulated by Services Australia under the program. Payment will not be made for claims that do not meet these requirements. Details required for each claim are based on the eligibility requirements of this program, as described within these guidelines (clauses 4,5,6,7,8 and 9).

From time to time, stoma associations may be required to make software changes to their existing claiming systems within a suitable timeframe.

For more information on details required for claim submission, please refer to servicesaustralia.gov.au/stoma.

9.2 Submission of an ostomy claim

Claims for payment of the supply of stoma-related products must be submitted to Services Australia in accordance with the submission methods described by Services Australia. Submission methods have been designed to satisfy the agency's security and identity authentication standards, and offer a secure and streamlined method to interact with the agency. Refer to Services Australia's website for further details on how to submit a claim servicesaustralia.gov.au/stoma.

Claims for reimbursement by Services Australia should be lodged by each stoma association on a monthly basis. Associations must keep supporting evidence for audit purposes.

9.3 Payment of an ostomy claim

Payments for all claims processed by Services Australia are paid via electronic funds transfer to the financial institution nominated by the stoma association. Payment statements are forwarded to the stoma association following payment to their nominated financial institution.

Electronic claims payment is within 21 days from date of receipt by Services Australia. Currently, claims are processed and completed for payment within **17 days of the submission** of a correctly completed and submitted claim. Where claims are processed via HPOS V2.0 (required for any new association and for all existing associations from 1 January 2021), claims may be paid within seven days of lodgement. If the claim is rejected and resubmitted, the claim will be processed within **17 days of the resubmission date**.

Payment statements contain details of items rejected for payment, any adjustments that may be made to a claim including the payment of the 2.75% administration fee. The statement may contain details of more than one claim.

9.4 Audit

Stoma-related products are subsidised by the Australian Government.
As such, the Department in collaboration with Services Australia may choose to review stoma associations' claims for payment for integrity purposes. A follow-up check may be made later if considered necessary. Reviews will include orders and invoices checking as to the items supplied to members over that period of time.

9.4.1 Evidence

Stoma associations are required to retain proof of claims and supporting evidence for a minimum of two years including:

- Completed members' application forms submitted by members, or their agents, for all (current and ceased) members.
- Records or proof of a member's request and the supply of stoma-related products for each claimed item.
- Medical evidence supporting increased supply and relevant approval from the Department.
- Evidence supporting increased supply for non-clinical reasons.

Stoma associations should also retain copies of the invoices provided by the suppliers of the stoma related products for at least the same period of time.

Reviews may be undertaken by the Department in collaboration with Services Australia.

After each annual general meeting where required by state laws, each incorporated stoma association may be required to complete the return to the Office of Consumer and Business Affairs in the state they are registered.

10. Forms

10.1 Services Australia and authorisation forms

Stoma associations are responsible for keeping supporting evidence for audit purposes. The following forms, available on the Services Australia website, are to be used by stoma associations to record and retain details that support business operations and which may be required for auditing purposes:

- **Stoma Appliance Scheme application – PB049 -** application to participate in the Stoma Appliance Scheme.
- **Stoma Appliance Scheme entitlement card form – PB044 -** entitlement card required for each participant of the Stoma Appliance Scheme.
- **Stoma Appliance Dual Entitlement Card – PB045 -** entitlement card for members who have more than one stoma.
- **Claim for payment – Stoma Appliance Scheme – PB043 -** claim for payment of products supplied to members.
- **Supply of stoma appliances and pharmaceutical preparations – PB046** - listing of items supplied associated with a claim for payment.
- **Application for additional stoma supplies – PB050** - application for the supply of stoma-related products outside the supply limits described in the SAS Schedule.
- **Authorisation forms** are available on the Stoma Appliance Scheme website Stoma Appliance Scheme, for the use of:
    - irrigation kits;
    - Tieman Tip catheters; and
    - Deodorant & Absorption Gelling Sachets.

  The use of irrigation kits, tieman tip catheters and Deodorant & Absorption Gelling Sachets by persons with a stoma requires special authorisation by a registered health practitioner or STN. These products should not be dispensed to a member prior to the sighting of the duly completed and signed authorisation form.

Note: Forms PB043 and PB046 will no longer be required where associations are submitting claims via HPOS V2.0 only.

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All information in this publication is correct as at October 2020