

FREQUENTLY ASKED QUESTIONS

PBS subsidy for medicines subject to a Serious Scarcity Substitution Instrument

What is a SSSI?

In the event of a serious shortage, the Therapeutic Goods Administration (TGA) may publish a Serious Scarcity Substitution Instrument (SSSI) which allows community pharmacists to substitute specific medicines without prior approval from the prescriber, as long as the permitted circumstances within the SSSI are met. This means that patients can receive their medicines from their pharmacist without delay, ensuring treatments are not interrupted. It also relieves workload pressure on prescribers and pharmacists.

Further information and a list of the SSSIs issued by the TGA may be accessed at:

www.tga.gov.au/serious-scarcity-substitution-instruments-sssis.

How is the substitution PBS subsidised?

The Australian Government has implemented changes that allow Pharmaceutical Benefits Scheme (PBS) subsidy in circumstances where the TGA has issued a SSSI. PBS subsidy will be determined by the Minister for Health for each SSSI that is issued by the TGA.

PBS subsidy is given effect through determinations made under section 89A of the *National Health Act 1953*, which allow specified PBS substitutable medicines to be supplied in place of a scarce medicine, as long as the substitution is in accordance with the TGA's SSSI and other PBS related criteria are met (see [Information for Pharmacists](#)).

How can you stay up-to-date?

TGA issued SSSIs are published at www.tga.gov.au/serious-scarcity-substitution-instruments-sssis.

SSSIs subsidised by the PBS are published at www.pbs.gov.au/info/browse/medicine-shortages. Any new SSSIs that are subsidised through the PBS will be communicated via the PBS news feed. PBS subsidy arrangements will cease once the relevant TGA SSSI is no longer in force for that medicine.

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Information for Pharmacists

What conditions should be met before medicines are substituted?

The permitted circumstances are specified by the TGA in each SSSI, and may be reviewed at: www.tga.gov.au/serious-scarcity-substitution-instruments-sssi.

There are additional conditions that must be met for the substitution to be subsidised under the PBS. These conditions are set out under Section 5 of the Determination and have been summarised below. Section 5 of the Determination may be reviewed at www.legislation.gov.au/Search/national%20health%20substitution.

Will it be mandatory to dispense medicines in accordance with an SSSI if there is one in place?

No. The pharmacy may have the scarce medicine in stock despite a national-level or local-level shortage. If the scarce medicine is in stock, the pharmacist is not permitted to supply the substitutable medicine under the PBS. If the scarce medicine is not in stock, the pharmacist will need to consider whether it is appropriate to supply the substitutable medicine to a patient in accordance with the SSSI.

Do pharmacists have an obligation to seek patients' consent to supply the substitutable medicine?

Yes. Before supplying a substitutable medicine, the pharmacist must discuss the proposed PBS substitution with the patient or their agent. The pharmacist must inform the person presenting the prescription of each substitutable medicine the patient may be entitled to access.

The pharmacist must also inform the patient of the amount they will be charged for:

- each substitutable medicine as either:
 - a PBS supply (for example, the patient co-payment that will be charged); or
 - a private prescription (which may be cheaper than the cost for a PBS supply); and
- The scarce medicine as a PBS supply.

This enables patients to make informed choices, in consultation with their healthcare professionals.

What records must be kept by the pharmacist to justify PBS subsidised supply of a substitutable medicine?

The pharmacist must retain the information used to support the decision to supply the substitutable medicine, including the following:

- a statement that the substitutable medicine supplied is a pharmaceutical benefit determined under paragraph 89A(3)(a) of the *National Health Act 1953*;
- a statement that the conditions in section 5 of the Determination are satisfied; and
- a statement that the pharmacist is satisfied that the substitutable medicine needs to be supplied because:
 - the pharmacist cannot supply the scarce medicine; and
 - it is not practicable for the person to obtain a prescription for the substitutable medicine from a PBS prescriber, before the person needs the supply of the scarce medicine.

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Do pharmacists have an obligation to notify the prescriber of the substitution?

Yes. The pharmacist must also inform the PBS prescriber who wrote the prescription, in writing, that the substitution has been made. The information must be provided within 72 hours after the supply.

Can approved hospital authorities (Section 94) supply under these arrangements?

No. These changes only apply to substitutable medicines dispensed by 'approved pharmacists' as defined under subsection 84(1) of the *National Health Act 1953*. This excludes approved hospital authorities.

How does the substitution work with electronic prescribing?

Pharmacists are allowed to annotate a prescription electronically as part of a dispensing activity to record the substitution. Annotations from other pharmacists, details of the last prescription dispensed and original prescription are also shown. Further information is available at: <https://developer.digitalhealth.gov.au/resources/faqs/electronic-prescribing-frequently-asked-questions>.

How will 'Authority Required' prescriptions be managed?

There may be circumstances where substitutable medicines under these arrangements are Authority required. Where an authority prescription number is required but not available, the default value of '00000246' should be used. The default authority prescription number may result in a PBS Online warning (reason code 151), which can be disregarded in these circumstances.

What item code should the pharmacist use to dispense a substitutable medicine?

The pharmacist is required to identify and dispense against the item code for the substitutable medicine with restriction criteria that is identical to that of the scarce medicine. Details of the item codes to be used to dispense the substitutable medicine with matching restriction criteria will be provided on the PBS website at www.pbs.gov.au/info/browse/medicine-shortages.

How will PBS payments be managed?

PBS payments for substitutable medicines will be managed through PBS Online.

FREQUENTLY ASKED QUESTIONS

Information for Patients

How do these arrangements help me?

Under these arrangements, patients with a PBS prescription for a scarce medicine will be able to receive a substitutable medicine at a PBS subsidised price without the need to obtain a new prescription from their prescriber.

Why are these arrangements in place?

These arrangements ensure that patients continue to have access to medicines, are able to make informed choices, and are not financially disadvantaged during periods of PBS medicine shortages.

These arrangements address situations where it is not practicable to obtain a PBS prescription for the substitutable medicine before the patient needs the supply. These changes will also relieve pressure on prescribers and allow patients to receive their medicines from their pharmacist in a timely manner.

How much will the substitution cost?

Patients eligible for PBS subsidy will receive subsidised supply and will pay no more than applicable PBS co-payments, which will contribute to their PBS Safety Net Threshold. Pharmacists will be required to inform patients of charges, prior to the substitution (see [Do pharmacists have an obligation to seek patients' consent to substitution of prescribed medicines?](#))

Information for Prescribers

Do pharmacists have an obligation to inform prescribers that a medicine has been substituted?

Yes. The pharmacist must inform (in writing) the PBS prescriber who wrote the prescription for the prescribed medicine that supply of the substitutable medicine has been made. The information must be provided within 72 hours after the supply.

Are there circumstances where the pharmacist should refer the patient back to the prescriber?

If the patient refuses to accept the substitutable medicine or, based on the pharmacist's professional judgement, there are reasons why supply under the SSSI is not appropriate (for example, the conditions outlined in the SSSI or the Determination are not met), the pharmacist must refer the patient back to the prescriber to discuss alternative treatment options.