



Australian Government
Department of Health

FREQUENTLY ASKED QUESTIONS NEW ARRANGEMENTS FROM 1 SEP 2015

PHARMACEUTICAL BENEFITS SCHEME (PBS) BOTULINUM TOXIN

The PBS Botulinum Toxin Programme helps eligible patients access PBS subsidised botulinum toxin to assist in the treatment of conditions such as facial spasms, incontinence, migraine, and symptoms associated with cerebral palsy. From 1 September 2015, the way PBS subsidised botulinum toxin is supplied will better align with other PBS arrangements, using PBS prescriptions and hospital pharmacy coordination points. PBS botulinum toxin products will not be supplied through community pharmacies, including community pharmacies acting as agents for public hospitals.

Patient and prescriber eligibility criteria will be unchanged. All botulinum toxin medicines supplied under the PBS will be subject to the new arrangements. A full list of the Programme medicines and PBS eligibility criteria are available at: www.pbs.gov.au

What is changing for prescribers?

From 1 September 2015, access to PBS botulinum toxin will be prescription based. Prescribers will need to write a prescription for each patient, for each treatment period, ensuring the prescriptions they write comply with PBS requirements for subsidised botulinum toxin, including patient and prescriber eligibility.

The correct prescription type is a PBS Authority [STREAMLINED] prescription, with the use of streamlined authority codes that are specific to the indication for use. These codes can be found in the attached extract from the PBS Schedule, and apply for prescriptions written on and from 1 September 2015, where the quantity required on prescription does not exceed the PBS maximum quantity given in the PBS Schedule.

PBS Authority [STREAMLINED] prescriptions can be generated by popular clinical practice software and printed on blank PBS prescription stationery. Alternatively, prescribers' personal pre-printed PBS Authority prescription pads may be used, with the correct streamlined code added after the name of the product required on the prescription.

The ordering, dispensing and claiming of PBS botulinum toxin must take place with the involvement of a Section 94 approved hospital authority (pharmacy). A range of delivery options will be open to prescribers, depending on the practice location, including direct manufacturer supply of botulinum toxin products to prescribers' rooms, rather than via the hospital pharmacy. Patients must not be placed in a position where they handle botulinum toxin products.

From 1 September 2015, patient co-payments will apply for each prescription of a botulinum toxin product, whether a patient is treated as a public or private patient. While hospital authorities are not required to collect a co-payment if they so choose, if co-payments are to be collected, local arrangements should be made between the

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hospital authority and prescribers for collection of the co-payments. Patients will need to be advised of local arrangements.

Prescribers may order botulinum toxin products from hospital pharmacies in advance of providing valid PBS prescriptions to cover these supplies. PBS Regulations require prescribers to make prescriptions available within 7 days of a verbal or written order.

PBS subsidised botulinum toxin packs must not be split across patients as multi-use is not permitted under PBS Regulations.

While the PBS permits multiple vials of botulinum toxin products to be prescribed for a patient, prescribers are reminded to prescribe only the quantity sufficient for the relevant procedure. This may not be known until the patient has been assessed on presentation.

In clinical circumstances where the quantity of botulinum toxin required for a patient's immediate treatment exceeds the PBS Maximum Quantity given in the PBS Schedule, prescribers must seek prior (telephone) approval to prescribe that quantity from the Department of Human Services [Telephone Authority Applications Freecall service 1800 888 333.]

What is not changing for prescribers?

Prescribers must continue to ensure the patients meet PBS eligibility criteria for use of subsidised botulinum toxin.

While restrictions on prescriber eligibility will remain, current processes will cease for prescriber registration with the Department of Human Services (Medicare). Prescribers are responsible for ensuring they meet the PBS Prescriber eligibility for each botulinum toxin product ordered. Note that separate state or territory requirements may apply.

Current stocks of PBS subsidised botulinum toxin held by prescribers may still be used when the new arrangements come into effect on 1 September 2015, until 31 December 2015.

Claims for use of PBS subsidised botulinum toxin supplied to prescribers prior to 1 September 2015 with all the relevant, complete and correct documentation will be accepted by the Department of Human Services up to the close of business on 31 December 2015.

Where can I seek further information?

You may direct any further queries to BTP@health.gov.au

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What is changing for pharmacy?

A Section 94 approved hospital authority must be involved in the ordering, and PBS claiming of botulinum toxin. Local arrangements may be made between the hospital authority and the prescriber for the delivery of botulinum toxin to, or collection by, the prescriber, noting that patients must not be placed in a position where they handle botulinum toxin products. Delivery direct from product manufacturers to prescribers' rooms is also permitted. Local arrangements may also be made between the hospital authority and prescribers for collection of patient co-payments, as needed.

The legislation for PBS botulinum toxin will be amended, as of 1 September 2015, to:

- (a) permit only hospital authorities to supply and make claims on the Commonwealth in respect of PBS subsidised botulinum toxin; and
- (b) extend the right of approved hospital authorities to supply and claim for botulinum toxin benefits on presentation of a valid PBS prescription for the treatment of all eligible patients, rather than being restricted to patients who are being treated in, or at, the hospital.

Hospital pharmacies will be remunerated in the same way that pharmacy is remunerated for supplying PBS subsidised Highly Specialised Drugs, and may raise a patient charge for those supplies in accordance with Commonwealth legislation. Pharmacists should note that a PBS benefit like botulinum toxin that is subject to Authority required or Authority [STREAMLINED] requirements cannot be supplied prior to the date of prescribing.

What is changing for patients?

Patients will continue to visit their specialist medical practitioner for assessment and treatment under the new arrangements. Patients will not be required to take a prescription to the hospital pharmacy.

Patient co-payments will apply for each prescription of a botulinum toxin product. PBS co-payments for 2015 are \$6.10 for concessional patients, and up to \$37.70 for non-concessional patients. Standard patient eligibility criteria and entitlement rules will also apply, enabling patients to use the Safety Net and patient refund arrangements. The prescriber will advise what local arrangements have been put in place for payment of the co-payment.

The PBS Safety Net provides further assistance to those Australians and Australian families who require a large number of PBS prescriptions over a calendar year.

After reaching the Safety Net threshold, general patients pay for further PBS prescriptions at the concessional co-payment rate and concession card holders are dispensed PBS prescriptions at no further charge for the remainder of that calendar year. In order to access the Safety Net arrangements, patients need to maintain records of their PBS expenditure on a Prescription Record Form. These forms are available from all pharmacies. A Safety Net Entitlement card or Safety Net Concession Card can be issued by the pharmacist once the threshold is reached.