



australasian society of clinical immunology and allergy

24 April 2020

Professor Andrew Wilson
Chair, Pharmaceutical Benefits Advisory Committee (PBAC)
MDP 952, GPO Box 9848
Canberra, ACT 2601
Email: pbac@health.gov.au

Dear Professor Wilson,

Re: Request for advice regarding access to adrenaline (epinephrine) auto-injectors on the Pharmaceutical Benefits Scheme (PBS)

I write to you on behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA), in response to your letter of 14 April 2020.

I hope that this letter answers your questions and provides clarification about the following two issues that were raised in your letter:

- **Maximum quantity of two adrenaline auto-injectors is allowed on the PBS.**
- **Most patients at risk of anaphylaxis should be prescribed two adrenaline auto-injectors.**

Maximum quantity of two adrenaline auto-injectors is allowed on the PBS

There appears to be confusion amongst some prescribers about the maximum number of adrenaline auto-injectors allowed on the PBS. To address this, we have included the following statement on the ASCIA website <https://www.allergy.org.au/members/adrenaline-autoinjector-availability#aa2>:

There have NOT been any recent changes to the PBS listings for EpiPen® and EpiPen® Jr adrenaline auto-injectors, which allow a maximum quantity of two auto-injectors, and both of these require an authority approval. When accessing the PBS website <http://www.pbs.gov.au/medicine/item/8698T> it is important that prescribers are aware that they have to click on “**Note**” on the top left hand side of the webpage, to access the following information:

The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device.

*Note - Authority approvals will be limited to a **maximum quantity of 2 auto-injectors** at any one time.*

Note - No applications for repeats will be authorised.

Most patients at risk of anaphylaxis should be prescribed two adrenaline auto-injectors

ASCIA Guidelines for adrenaline auto-injector prescription include the following information:

Two devices per prescription are routinely recommended. This allows one device to be with the patient (or for parental use at home for younger children), and one device to be available for use at the early childhood education/care centre or school. Additional devices (if desired) may be purchased privately without prescription in Australia, since more than two devices at a time are not PBS subsidised in Australia.

In adults and older high school students, two devices are strongly recommended in those with:

- Previous hypotensive or near fatal anaphylaxis.
- Need for more than one adrenaline dose to treat previous anaphylaxis episodes.
- Limited access to medical care (e.g. travel or residence in remote areas, perhaps overseas travel in some circumstances).
- Patients with systemic mastocytosis.
- Where high body mass indicates that the routine 0.3mg adrenaline dose will provide an insufficient dose for adequate treatment. (Note: Many patients over 50Kg require a 2nd dose).

ASCIA Guidelines for adrenaline auto-injector prescription are available on the ASCIA website:

<https://www.allergy.org.au/hp/anaphylaxis/adrenaline-autoinjector-prescription>

In 2020 ASCIA has stated “The treating doctor or nurse practitioner hereby authorises prescription of adrenaline auto-injectors” on the red ASCIA Action Plan for Anaphylaxis, to reinforce what is stated in the ASCIA Guidelines for adrenaline auto-injector prescription. These plans are available on the ASCIA website: <https://www.allergy.org.au/hp/anaphylaxis/ascia-action-plan-for-anaphylaxis>

ASCIA response to correspondence

Based on the above information, ASCIA’s response to the correspondence from the clinician (who is concerned that some prescribers are unaware of the provision to request a second auto-injector, and therefore may only prescribe one auto-injector in situations where a patient would benefit from having two), would be as follows:

The maximum quantity for all adrenaline auto-injectors on the PBS does not need to be increased to two devices, as that is already in place. However, when accessing the PBS website <http://www.pbs.gov.au/medicine/item/8698T> it is important that prescribers are aware that they have to click on “**Note**” on the top left hand side of the webpage, to access the following information:

Note - Authority approvals will be limited to a **maximum quantity of 2 auto-injectors** at any one time.

Note - No applications for repeats will be authorised.

Most patients (children and adults) at risk of anaphylaxis should be prescribed two adrenaline auto-injectors. The circumstances under which patients may require two auto-injectors are listed in the ASCIA Guidelines for adrenaline auto-injector prescription, which are available open access on the ASCIA website: <https://www.allergy.org.au/hp/anaphylaxis/adrenaline-autoinjector-prescription>

I hope that this letter addresses the questions raised in your letter of 14 April 2020. Please contact us you have any further questions.

Yours sincerely,



Dr Brynn Wainstein
ASCIA President

Copy: Dr Katie Frith, Chair, ASCIA Anaphylaxis committee; ASCIA Directors; Jill Smith, ASCIA CEO