

17 September 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: ASCIA response to Anapen adrenaline (epinephrine) autoinjector application to PBAC

The Australasian Society of Clinical Immunology and Allergy (ASCIA) has recently been informed by Allergy Concepts that they have submitted an application for Anapen adrenaline autoinjectors, for consideration by the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC), for TGA approval and listing on the Pharmaceutical Benefits Scheme (PBS).

We note that the Anapen application has been included in the agenda of the PBAC meeting scheduled for November 2020 and the closing date for comments is 7 October 2020.

ASCIA welcomes the availability of Anapen as an alternative adrenaline autoinjector in Australia. Having just one brand of adrenaline autoinjector (EpiPen), has meant that in times of product shortages, there has been no alternative for Australians at risk of potentially life threatening severe allergic reactions (anaphylaxis). This has caused risks, as well as panic buying and stockpiling, which has disadvantaged many Australians.

An advantage of Anapen is the availability of a 500mcg version, which meets a currently unmet clinical need, for a higher dose than the 300mcg device. For example:

- If an older child or adult weighing more than 50kg requires adrenaline, they will usually require two injections of the highest strength device (300mcg), that is currently available. If a second device is unavailable, the timing for the person to be treated with adrenaline in an ambulance may be critical, whilst being transported to hospital.
- It is expected that most Australian adults weigh at least 50kg, and therefore a 500mcg device could be suitable to prescribe for most adults and some older children.
- Having a 500mcg device could also mean that a person only needs to carry one device, which may be more convenient and therefore improve their quality of life.
- For people in rural, regional or remote locations, having 500mcg devices should provide them with a sufficient dose of adrenaline and provide reassurance, in case an ambulance is not readily available and takes longer to arrive.

As most people who administer adrenaline autoinjectors are not health professionals, education and training is required, to avoid incorrect use that can result in fatalities or disabilities, due to inadvertently undertreating anaphylaxis. Allergy Concepts are aware that ASCIA is the main provider of accessible,

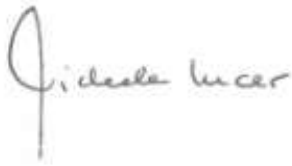
consistent and evidence-based online anaphylaxis resources, education and training for health professionals and the community, which are available at www.allergy.org.au/anaphylaxis

This website contains world leading, open access and free of charge online resources, education and training, including ASCIA Action Plans for Anaphylaxis and ASCIA anaphylaxis e-training courses that have specific modules on the use of adrenaline autoinjectors.

Allergy Concepts are also aware that these resources and courses will require updating if the Anapen application is approved, and are prepared to provide an unrestricted educational grant to ASCIA, to support the costs of these updates.

Please do not hesitate to contact us by emailing jill@allergy.org.au or phoning 0425216402 if you require further information.

Yours sincerely,



Professor Michaela Lucas
ASCIA President



Dr Katie Frith
Chair, ASCIA Anaphylaxis Committee



Dr Brynn Wainstein
Immediate past ASCIA President



Jill Smith
ASCIA CEO
jill@allergy.org.au
0425216402