14.02 ADRENALINE
I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector and I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector.
EMERADE®, Link Medical Products Pty Ltd

1 Purpose of Application

1.1 The submission requested a temporary Section 85 Authority Required listing of adrenaline (EMERADE®, 150 mcg in 0.15 mL and 300 mcg in 0.3 mL auto-injectors) on the Pharmaceutical Benefits Schedule (PBS) as an alternative to currently listed adrenaline (EpiPen® and EpiPen Junior®), to address the current supply shortage issue of adrenaline products.

2 Requested Listing

2.1 The submission requested identical listing price, pack size and authority conditions as EpiPen.

3 Background

3.1 The Therapeutic Goods Administration (TGA) indicated that there is a current shortage of EpiPen (adrenaline 0.3mg/0.3mL injection syringe auto-injector – ARTG 42978) and EpiPen Jr (adrenaline 0.15mg/0.3mL injection syringe auto-injector – ARTG 42980). Epipen (ARTG 42978) has a shortage notification on the TGA's Medicine Shortages Information Initiative (MSII) website.

3.2 Alphapharm is currently the only sponsor marketing adrenaline auto-injector in Australia. Alphapharm's supply of Epipen and Epipen Jr is currently experiencing a supply shortage due to manufacturing issues. The TGA was concerned on the potential future shortage of this life-saving emergency product.

3.3 On 1 March 2018, the TGA approved the importation and supply of Emerade (adrenaline 150 mcg in 0.15 mL and 300 mcg in 0.3 mL auto-injectors) in Australia, under Section 19A(1) of the Therapeutic Goods Act 1989, from 1 March 2018 to 31 August 2018.

3.4 A letter of request from the sponsor (was received by the PBAC Secretariat in 6 March 2018 to request a temporary PBS listing of EMERADE adrenaline (300 mcg and 150 mcg auto injector) in the interest to address the current supply shortage in Australia of registered EPIPEN and EPIPEN Jr.

3.5 Emerade is a United Kingdom based product, which has a different device to EpiPen. While, the sponsor has other adrenaline products in the form of ampoules that are

currently listed on the PBS, this was the first consideration by the PBAC of EMERADE (adrenaline auto-injectors).

4 Pricing considerations

4.1 There will be no pricing implications, as the sponsor proposed the same price as currently listed EpiPen and EpiPen Jr (DPMQ $97.10) and this listing is not expected to grow the market.

5 PBAC Outcome

5.1 The PBAC recommended the temporary General Authority Required listing of Emerade (adrenaline, 300 mcg and 150 mcg auto injectors) on the Pharmaceutical Benefit Schedule (PBS) to address the shortage supply issue for the PBS listed adrenaline auto injectors.

5.2 The PBAC considered that there is a clinical need for the supply of an adrenaline auto-injector to be maintained on the PBS. The PBAC considered that the listing should remain during the validity of the Section 19A(1) approval by the TGA. For a longer term listing of the product, a submission to the PBAC would be required.

5.3 The PBAC considered that listings should be the same Authority Required benefit conditions as EpiPen and EpiPen Jr, namely suitable for inclusion for prescribing by nurse practitioners.

5.4 The restrictions for Emerade and EpiPen should include a caution stating that the products have different administration techniques and should not be dispensed to the same patient without appropriate training in their use.

Outcome:

Recommended

6 Recommended listing

6.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
ADRENALINE Injection 150 microgram/0.3 mL Injection 300 microgram/0.3mL	1	0	Emerade	Link Medical Products Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐Midwives
PBS Indication:	Acute allergic reaction with anaphylaxis
Treatment phase:	Initial sole PBS-subsidised supply for anticipated emergency treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☒Authority Required - Telephone ☒Authority Required – Emergency ☒Authority Required - Electronic ☐Streamlined
Clinical criteria:	Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.
Prescriber Instructions	The name of the specialist consulted must be provided at the time of application for initial supply.
Administrative Advice	No applications for repeats will be authorised. 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. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au). Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.
Cautions	*EpiPen and Emerade products have different administration techniques and should not be prescribed to the same patient without appropriate training in their use.*

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PBS Indication:	Acute allergic reaction with anaphylaxis
Treatment phase:	Initial sole PBS-subsidised supply for anticipated emergency treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☒Authority Required - Telephone ☒Authority Required – Emergency ☒Authority Required - Electronic ☐Streamlined
Clinical criteria:	Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.
Administrative Advice	No applications for repeats will be authorised. 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. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au). Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.
Cautions	*EpiPen and Emerade products have different administration techniques and should not be prescribed to the same patient without appropriate training in their use*

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
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Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐Midwives
PBS Indication:	Acute allergic reaction with anaphylaxis
Treatment phase:	Continuing sole PBS-subsidised supply for anticipated emergency treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☒Authority Required - Telephone ☒Authority Required – Emergency ☒Authority Required - Electronic ☐Streamlined
Clinical criteria:	Patient must have previously been issued with an authority prescription for this drug.
Administrative Advice	No applications for repeats will be authorised. 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. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au). Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.
Cautions	*EpiPen and Emerade products have different administration techniques and should not be prescribed to the same patient without appropriate training in their use.*

6.2 Amend existing listing as follows:
Update administrative advice and caution for item codes 8697R, 8698T to include the brand name Emerade

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.