

## 5.16 ADRENALINE (EPINEPHRINE),

**I.M. injection 150 micrograms in 0.15 mL (as acid tartrate) single dose syringe auto injector, Jext® Junior,**

**I.M. injection 300 micrograms in 0.3 mL (as acid tartrate) single dose syringe auto injector, Jext®,**

**Health Technology Analysts Pty Limited**

### 1 Purpose of Submission

- 1.1 The Category 4 submission requested a General Schedule Authority Required (Telephone/Online) listing of a new form of adrenaline (epinephrine) acid tartrate 150 micrograms/0.15 mL auto-injector (AI) (Jext® Junior (Jr)) and 300 micrograms/0.3 mL AI (Jext®) under the same circumstances as the currently listed adrenaline (epinephrine) 150 microgram/0.3 mL AI (EpiPen® Jr and Anapen® Jr 150) and 300 microgram/0.3 mL AI (EpiPen® and Anapen® 300) respectively.

**Table 1: Key components of the clinical issue addressed by the submission**

Component	Description
Population	Patients with a significant risk of anaphylaxis
Intervention	Jext® Jnr 150 microgram/0.15mL auto-injector Jext® 300 microgram/0.30mL auto-injector
Comparator	Anapen Jr® 150 microgram/0.30 mL injection, pen device Anapen® 300 microgram/0.30mL injection, pen device EpiPen Jr® 150 microgram/0.30 mL injection, pen device EpiPen® 300 microgram/0.30mL injection, pen device Adrenaline Jr Viatris® 150 microgram/0.30 mL injection, pen device Adrenaline Viatris® 300 microgram/0.30mL injection, pen device
Outcomes	Pharmacokinetics Incorrect administration of the auto-injector
Clinical claim	Non-inferiority: In 'patients with a significant risk of anaphylaxis, Jext® is non-inferior to EpiPen® and Anapen® in terms of effectiveness and non-inferior in terms of safety

Source: Table 1-2, p8 of the submission main body.

### 2 Background

#### **Registration status**

- 2.1 Jext Jr and Jext are not yet registered in the Australian Register of Therapeutic Goods (ARTG). The submission stated that an application had been lodged with the

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Therapeutic Goods Administration (TGA) and approval is anticipated in the fourth quarter of the year. A TGA Delegate's overview was available.

- 2.2 The proposed TGA indication based on the Product Information (PI) of Jext (and Jext Jr) is the same as EpiPen (and EpiPen Jr) and Adrenaline Viatris (and Adrenaline Jr Viatris) which is, "emergency treatment of anaphylaxis (acute severe allergic reactions) due to insect stings, or bites, foods, drugs or other allergens".
- 2.3 The TGA Delegate's Overview recommended approving the registration of Jext Jr and Jext, subject to the resolution of outstanding issues regarding good manufacturing practice (GMP) clearance.
- 2.4 The submission claimed that Jext Jr is equivalent to Anapen Jr and EpiPen Jr; and Jext is equivalent to Anapen 300 and EpiPen. The TGA Delegate's Overview stated that it could not make a statement of therapeutic equivalence of Jext Jr and Jext compared to EpiPen Jr and EpiPen for the purpose of listing the medicine as a pharmaceutical benefit. The pre-PBAC response stated that the overall data from the PK and PD studies, as well as the study comparing ease of handling show that Jext and Jext Jr should be considered therapeutically equivalent to EpiPen and Anapen. The pre-PBAC response stated that Jext demonstrated a successful administration when compared to EpiPen, shared a comparable bioavailability profile to Anapen and other brands of AIs and there was no significant difference in the rate of successful injection between Jext and EpiPen (pre-PBAC response).

***Previous PBAC consideration***

- 2.5 Jext Jr and Jext have not been previously considered by the PBAC.
- 2.6 Adrenaline 150 AI (Anapen Jr 150, EpiPen Jr and Adrenaline Jr Viatris) and adrenaline 300 AI (Anapen 300, EpiPen and Adrenaline Viatris) are currently listed on the PBS as Authority Required listings for acute allergic reaction with anaphylaxis.

**3 Requested listing**

- 3.1 The submission requested the listing of Jext Jr and Jext under the same circumstances as the currently listed EpiPen® Jr and Anapen® 150; and EpiPen and Anapen 300 respectively.
- 3.2 The submission proposed a minor change to the 'caution' wording under the existing listings due to the differences in device activation and administration techniques between Jext and the other brands of adrenaline. The PBAC may recall that in its November 2020 consideration, while the PBAC noted the differences in administration techniques of Anapen, EpiPen and Adrenaline Mylan, it considered that patients with sufficient anaphylaxis education/training resources would be able to administer different devices appropriately (paragraph 6.4, adrenaline public summary document (PSD), November 2020 PBAC meeting). The PBAC further reiterated in an addendum to the November 2020 minutes that it was satisfied that the differences in administration techniques of Anapen, EpiPen and Adrenaline Mylan would be

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appropriately managed based on the clinical, safety and risk management information in the TGA Delegate's Overview (paragraph 9.5, adrenaline PSD, November 2020).

- 3.3 An abridged version of the requested listing is presented below. Suggested additions are in italics and deletions are in strikethrough:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>ADRENALINE (EPINEPHRINE)</b>					
adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device	8697R	2	2	0	Adrenaline Jr Viatris <sup>a</sup> Anapen Junior 150 <sup>a</sup> EpiPen Jr <sup>a</sup>
<i>adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device</i>	<i>NEW</i>	2	2	0	<i>Jext Jr<sup>a</sup></i>
adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device	8698T	2	2	0	Adrenaline Viatris <sup>b</sup> Anapen Junior 300 <sup>b</sup> EpiPen <sup>b</sup>
<i>adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device</i>	<i>NEW</i>	2	2	0	<i>Jext<sup>b</sup></i>
<b>Restriction Summary 7371 / Treatment of Concept: 4909</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Authority Required				
	<b>Indication:</b> Acute allergic reaction with anaphylaxis				
	<b>Caution:</b> <del>Non-Anapen and</del> Anapen, <i>Epipen and Jext</i> products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.				
	<b>Note:</b> <i>Pharmaceutical Benefits that have the brand Jext Jr may be substituted for the Pharmaceutical Benefits that have the brands Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr</i>				
<b>Restriction Summary 8695 / Treatment of Concept: 8734</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Authority Required				
	<b>Indication:</b> Acute allergic reaction with anaphylaxis				
	<b>Caution:</b> <del>Non-Anapen and</del> Anapen, <i>Epipen and Jext</i> products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.				
	<b>Note:</b> <i>Pharmaceutical Benefits that have the brand Jext Jr may be substituted for the Pharmaceutical Benefits that have the brands Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr</i>				
<b>Restriction Summary 7351 / Treatment of Concept: 4947</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Authority Required				
	<b>Indication:</b> Acute allergic reaction with anaphylaxis				
	<b>Caution:</b> <del>Non-Anapen and</del> Anapen, <i>Epipen and Jext</i> products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.				

<b>Note:</b> <i>Pharmaceutical Benefits that have the brand Jext Jr may be substituted for the Pharmaceutical Benefits that have the brands Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr</i>
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- 3.4 In its November 2020 consideration, the PBAC noted the issues of brand substitution ('a' flagging) and shortage of supply of adrenaline products from its previous considerations of adrenaline auto-injectors. Although, the November 2020 submission had requested for Anapen not to be considered equivalent to other adrenaline auto-injector brands for the purposes of substitution, the PBAC considered that the substitutability of Anapen and EpiPen would assist in the timely dispensing of adrenaline during the shortages of other PBS listed brands. (paragraph 6.4, adrenaline PSD, November 2020 PBAC meeting).
- 3.5 The PBAC, in an addendum to the November 2020 minutes, advised that under Section 101(4AACD) of the *National Health Act 1953*, in the Schedule of Pharmaceutical Benefits, Anapen 300 should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution for the treatment of acute allergic reaction with anaphylaxis with EpiPen 300 and Adrenaline Mylan 300; and Anapen Jr should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution for the treatment of acute allergic reaction with anaphylaxis with EpiPen Jr and Adrenaline Jr Mylan (paragraph 9.5, adrenaline PSD, November 2020). In this addendum, the PBAC reiterated that the substitutability of Anapen, EpiPen and Adrenaline Mylan would assist in the timely dispensing of adrenaline during shortages (paragraph 9.6, adrenaline PSD, November 2020).

## 4 Comparator

- 4.1 The submission nominated Adrenaline Jr Viatris, Anapen Jr 150 and EpiPen Jr as the main comparator for Jext Jr; and Adrenaline Viatris, Anapen 300 and EpiPen as the main comparator for Jext. The pre-PBAC response stated that should Jext Jr and Jext be recommended and PBS-listed, the listing would most likely replace the currently listed adrenaline AI brands (EpiPen, Anapen and Adrenaline Viatris) (pre-PBAC response).
- 4.2 The PBAC considered the nominated comparators were appropriate.

## 5 Consideration of the evidence

### *Sponsor hearing*

- 5.1 There was no hearing for this item.

### *Consumer comments*

- 5.2 The PBAC noted and welcomed the input from a medical organisation (1) via the Consumer Comments facility on the PBS website. The joint comment from Allergy & Anaphylaxis Australia (A&AA), the Australasian Society of Clinical Immunology and Allergy (ASCIA) and the National Allergy Council supported the listing of Jext Jr and

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Jext, highlighting the new listing would offer an additional treatment option for patients and reduces the risk of supply shortages. The input also noted that resources need to be updated to educate healthcare professionals and patients about the administration of a new device, noting that the sponsor of the new listing must be aware of the substantial additional costs for ASCIA, A&AA and the National Allergy Council and the time required to update the relevant resources.

**Clinical trials**

5.3 The submission was based on evidence from two clinical studies (JX-A-01 and REP68073) and two pharmacokinetic (PK) studies (JX-A-02 and JX-A-03) to demonstrate that Jext is non-inferior and is therapeutically equivalent to the PBS listed adrenaline 150 and 300 AIs (Table 2). Additionally, a usability study of its new label/instructions (REP68073) was provided.

**Table 2: Trials presented in the submission**

Trial ID	Protocol title	Trial dates
<b>Clinical study</b>		
JX-A-01 (NCT01887405)	Comparative Evaluation of Handling Characteristics of two adrenaline auto-injectors - a randomised, comparative, open-label, 2-way crossover, single-centre, non-inferiority study.  Victoria Strand, MD Phd, Asthma and Allergy Clinic, St. Göran's Hospital, Stockholm, Sweden	2013
REP68073	Summary of Jext Sticker label usability study ALK Nordic A/S, Danmark Filial	2017
<b>Pharmacokinetic studies</b>		
JX-A-02	Pilot double-blind pharmacokinetic investigation of the absorption and bioavailability of adrenaline delivered from Jext and Anapen® in healthy adult volunteers - a randomised, double-blinded, placebo-controlled phase I trial  Dr Salvatore Febbraro; Dr Kathryn Harries Simbec Research Limited Merthyr Tydfil CF48 4DR, UK	2012
JX-A-03	Open-label trial investigating the pharmacokinetic profile of adrenaline obtained following administration by the Jext autoinjector and by manual intramuscular injection in subjects with varying skin to muscle depths - a randomised, open-label trial.  Dr Simone Flöttmann PAREXEL International, Early Phase Clinical Unit – Berlin Spandauer Damm 130 Klinikum Westend, Haus 31 14050 Berlin Germany	2017

Source: Modified from Table 2-1, p15 & p16 of the submission main body.

5.4 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

### **Clinical claim**

- 5.5 The submission claimed non-inferior comparative effectiveness and safety of Jext compared with Anapen and EpiPen based on the pharmacokinetic (PK), pharmacodynamics (PD) and safety data. The TGA evaluator found no significant issues between Jext and Anapen and EpiPen and recommended approving the registration of Jext Jr and Jext, subject to resolution of outstanding issues regarding GMP clearance.
- 5.6 The PBAC considered that the claims of non-inferior comparative effectiveness and safety were supported by the assessment of the data by the TGA.

### **Economic analysis**

- 5.7 While the submission did not present an economic approach, the submission requested the same approved ex-manufacturer price (AEMP) for Jext Jr and Jext as the existing listings of adrenaline 150 and 300 AI brands respectively.
- 5.8 The PBAC previously recommended Anapen 300 and Anapen 500 on a cost-minimisation basis to EpiPen; and Anapen Jr 150 to EpiPen Jr (paragraph 9.2, adrenaline PSD, November 2020).
- 5.9 The submission proposed the following equi-effective doses for Jext Jr and Jext:
- 1 x 150 micrograms/0.15 mL AI (Jext Jr) = 1 x 150 microgram/0.3 mL AI (Anapen Jr 150 or EpiPen Jr or Adrenaline Jr Viartis)
  - 1 x 300 micrograms/0.3 mL AI (Jext) = 1 x 300 micrograms/0.3 mL AI (Anapen 300 or EpiPen or Adrenaline Viartis).
- 5.10 This was consistent with previous PBAC advice (paragraph 9.3, adrenaline PSD, November 2020) that the equi-effective doses are:
- one Anapen 300 and one Anapen 500 and one EpiPen 300 and one Adrenaline Mylan 300
  - one Anapen Junior and one EpiPen Jr and one Adrenaline Jr Mylan
- 5.11 As a Category 4 submission, the economic analysis has not been independently evaluated.

### **Estimated PBS usage and financial implications**

- 5.12 The submission adopted a market share approach to estimate the utilisation and financial impact of listing Jext Jr and Jext. The submission anticipated that the proposed listing would not increase the current utilisation of the adrenaline market and therefore the proposed listing would result in no financial implication to the PBS/RPBS over a period of six years (Table 3).
- 5.13 The pre-PBAC response reiterated that the new listing is not expected to increase the overall size of the adrenaline AI market in Australia because the new listing is

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requested under the same circumstances as all the other listed adrenaline AIs. The pre-PBAC response further stated that the new listing is not expected to change the number of patients at risk of anaphylaxis, and therefore will not change the number of adrenaline AIs dispensed as the utilisation of the new listing is expected to be completely offset by a reduction in the utilisation of EpiPen, Anapen and Adrenaline Viatrix. The pre-PBAC response recalled that the PBAC have previously noted that the listing of Anapen Junior and Anapen would not grow the current market and should result in a nil net cost to the Government (pre-PBAC response).

5.14 The financial impact to Services Australia will be determined by that agency as part of the post-PBAC process.

**Table 3: Estimated use and financial implications**

	2025	2026	2027	2028	2029	2030
<b>Scripts</b>						
Number of Scripts	1	2	3	4	5	5
<b>Estimated financial implications to PBS</b>						
New listing	6	6	6	6	6	6
Changed listing	7	7	7	7	7	7
Net cost to PBS	6	6	6	6	6	6
<b>Estimated financial implications to RPBS</b>						
New listing	6	6	6	6	6	6
Changed listing	7	7	7	7	7	7
Net cost to RPBS	6	6	6	6	6	6
<b>Net financial implications</b>						
Net cost PBS/RPBS	6	6	6	6	6	6

Source: Submission's financial model spreadsheet.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

The redacted values correspond to the following ranges

<sup>1</sup> 5,000 to < 10,000

<sup>2</sup> 10,000 to < 20,000

<sup>3</sup> 20,000 to < 30,000

<sup>4</sup> 30,000 to < 40,000

<sup>5</sup> 40,000 to < 50,000

<sup>6</sup> \$0 to < \$10 million

<sup>7</sup> net cost saving

### Quality use of medicines

5.15 The submission stated that a comprehensive support package aimed at improving the management of anaphylaxis will be provided. The package will consist of a complimentary Jext trainer pen, anaphylaxis action plans, prescriber and pharmacist checklists, and an instructive video in collaboration with the Australasian Society of Clinical Immunology and Allergy and Allergy & Anaphylaxis Australia to enhance the necessary skills required for effective anaphylactic response.

5.16 The submission further stated that accredited training opportunities to personnel across Australian allergy centres, asthma clinics, and primary care settings would be

provided as required, with the primary objective of enabling healthcare professionals to effectively manage anaphylactic incidents.

## 6 PBAC Outcome

- 6.1 The PBAC recommended the General Schedule Authority Required (Telephone/Online) listing of a new form of adrenaline (epinephrine) acid tartrate 150 micrograms/0.15 mL auto-injector (AI) (Jext Jr<sup>®</sup>) and 300 micrograms/0.3 mL AI (Jext<sup>®</sup>) under the same circumstances as the currently listed adrenaline (epinephrine) 150 microgram/0.3 mL (EpiPen<sup>®</sup>Jr, Anapen<sup>®</sup>Jr 150 and Adrenaline Jr Viatris<sup>®</sup>) and 300 micrograms/0.3 mL AI (EpiPen<sup>®</sup>, Anapen<sup>®</sup>300 and Adrenaline Viatris<sup>®</sup>) for the treatment of acute allergic reaction with anaphylaxis.
- 6.2 The PBAC considered that the claims of non-inferior comparative effectiveness and safety were acceptable based on the TGA Delegate's Overview (DO). The PBAC noted that the TGA evaluator recommended approving the registration of Jext Jr and Jext.
- 6.3 The PBAC noted the submission's proposed changes to the 'caution' wording under the existing listings to highlight the differences in device activation and administration techniques between Jext and the other brands of adrenaline AIs. The PBAC recalled in its November 2020 consideration, while the PBAC noted the differences in administration techniques of Anapen, EpiPen and Adrenaline Mylan, it considered that patients with sufficient anaphylaxis education/training resources would be able to administer the different devices appropriately (paragraph 6.4, adrenaline PSD, November 2020 PBAC meeting). The PBAC recalled that it was satisfied that the differences in administration techniques of Anapen, EpiPen and Adrenaline Mylan would be appropriately managed based on the clinical, safety and risk management information in the TGA DO (paragraph 9.5, adrenaline PSD, November 2020). The PBAC therefore considered the proposed changes to the 'caution' wording to highlight the differences in device activation and administration techniques for Jext would not be required.
- 6.4 The PBAC noted the submission's request for brand substitution ('a' flagging) for Jext Jr and Jext to the other adrenaline AIs. The PBAC recalled its previous recommendations that adrenaline AIs are substitutable and remained satisfied that the differences in administration techniques of adrenaline AIs can be appropriately managed in practice. The PBAC has therefore advised, consistent with previous advice, that under Section 101(4AACD) of the *National Health Act 1953*, in the Schedule of Pharmaceutical Benefits:
  - Jext Jr should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution with EpiPen Jr, Anapen Jr 150 and Adrenaline Viatris Jr.

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- Jext should be treated as equivalent at the pharmacy level (i.e. 'a' flagged in the Schedule) for the purpose of substitution with EpiPen, Anapen 300 and Adrenaline Viatris.
- 6.5 The PBAC noted that the TGA DO stated it could not make a statement of therapeutic equivalence of Jext Jr and Jext compared to EpiPen Jr and EpiPen for the purpose of listing the medicine as a pharmaceutical benefit. The PBAC considered Jext Jr and Jext to be therapeutic equivalent to EpiPen Jr and EpiPen, respectively.
- 6.6 The PBAC advised that, consistent with PBAC's previous recommendation of Anapen 300, Anapen 500 and Anapen Jr 150 at its November 2020 meeting, the equi-effective doses for Jext Jr and Jext to be the following,
- 1 x 150 micrograms/0.15 mL AI (Jext Jr) = 1 x 150 microgram/0.3 mL AI (Anapen Jr 150 or EpiPen Jr or Adrenaline Jr Viatris)
  - 1 x 300 micrograms/0.3 mL AI (Jext) = 1 x 300 micrograms/0.3 mL AI (Anapen 300 or EpiPen or Adrenaline Viatris).
- 6.7 The PBAC considered that the listing of Jext Jr and Jext is expected not to increase the overall market utilisation given that Jext Jr and Jext would likely substitute the currently listed adrenaline AIs. The PBAC therefore considered the new listing should result in no financial implication to the Government.
- 6.8 The PBAC noted that the sponsor was committed to working in collaboration with Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia to develop a comprehensive support package aimed at improving the management of anaphylaxis education and training resources around how to use Jext.
- 6.9 The PBAC advised that Jext Jr and Jext is suitable for prescribing by nurse practitioners, in line with the recommendation for Anapen and EpiPen
- 6.10 The PBAC advised that the Early Supply Rule should not apply to Jext Jr and Jext, as it does not apply to Anapen and EpiPen, because it is used for recurrent episodic use and there is a clinical imperative to ensure ongoing supply.
- 6.11 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Jext Jr and Jext are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Anapen Jr 150, EpiPen Jr and Adrenaline Jr Viatris; Anapen 300, EpiPen and Adrenaline Viatris or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health*

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*(Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

- 6.12 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.

**Outcome:**

Recommended

## 7 Recommended listing

### 7.1 Add new medicinal product pack:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
<b>ADRENALINE (EPINEPHRINE)</b>					
adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device	8697R	2	2	0	Adrenaline Jr Viatris <sup>a</sup> Anapen Junior 150 <sup>a</sup> EpiPen Jr <sup>a</sup>
<i>adrenaline (epinephrine) 150 microgram/0.15 mL injection, 0.15 mL pen device</i>	<i>NEW</i>	2	2	0	<i>Jext Jr<sup>a</sup></i>
adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device	8698T	2	2	0	Adrenaline Viatris <sup>b</sup> Anapen Junior 300 <sup>b</sup> EpiPen <sup>b</sup>
<i>adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device</i>	<i>NEW</i>	2	2	0	<i>Jext<sup>b</sup></i>
<b>Restriction Summary 7371 / Treatment of Concept: 4909</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Authority Required				
<b>Indication:</b> Acute allergic reaction with anaphylaxis					
<b>Caution:</b> Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.					
<b>Note:</b> <i>Pharmaceutical Benefits that have the brand Jext Jr may be substituted for the Pharmaceutical Benefits that have the brands Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr</i>					
<b>Restriction Summary 8695 / Treatment of Concept: 8734</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Authority Required				
<b>Indication:</b> Acute allergic reaction with anaphylaxis					
<b>Caution:</b> Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.					
<i>New CC01</i>	<b>Note:</b> <i>Pharmaceutical Benefits that have the brand Jext Jr may be substituted for the Pharmaceutical Benefits that have the brands Adrenaline Jr Viatris, Anapen Junior 150, EpiPen Jr</i>				
<b>Restriction Summary 7351 / Treatment of Concept: 4947</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse Practitioners				
	<b>Restriction Type:</b> <input checked="" type="checkbox"/> Authority Required				
<b>Indication:</b> Acute allergic reaction with anaphylaxis					
<b>Caution:</b>					

	Non-Anapen and Anapen products have different administration techniques. These products should not be prescribed to the same patient without training in their use. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.
	<b>Note:</b> <i>Pharmaceutical Benefits that have the brand Jext Jr may be substituted for the Pharmaceutical Benefits that have the brands Adrenaline Jr Viatrix, Anapen Junior 150, EpiPen Jr</i>

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## **8 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **9 Sponsor's Comment**

The sponsor had no comment.