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North-East London (NEL) Prescribing Guidance for Adrenaline Autoinjectors (AAIs) in Primary Care

Document Control

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SUMMARY

For Primary Care health professionals (FAQs for HCPs in Appendix 2):

- Adults and children should be prescribed at least TWO AAIs as standard to provide the most effective
 available treatment for anaphylaxis and the best chance that it is used appropriately
- Patients should be advised that they should always have immediate access to their AAI's
- School age children may require an additional TWO AAI's to be held on school premises for the purposes of safety and access to AAIs
- AAIs should be prescribed by **brand name only** as devices and administration instructions may vary
- In children there are different doses of AAIs. The dose is prescribed according to the patient's body
 weight and not age and there are different brands. In adults there is currently only one dose but
 different brands that are administered differently
- The allergy action plan of any adult or child should be reviewed each time a new prescription for AAI is requested. If the adult patient or child's carers report that there have been no changes in the allergies or their management, then a new plan is not needed but the medical documentation needs to specify that the action plan has been reviewed, and no changes were required based on the information provided
- Any health professional can use the British Society of Allergy and Clinical Immunology (BSACI)
 website to produce a free printable writable pdf document allergy action plan for an adult/child that
 can also be saved in medical documentation OR on the Ardens AAI template in EMIS under Clinical
 Effectiveness,

For children with allergies:

- The parents/carers must be trained on how to use the specific brand of prescribed AAI
- It is recommended that parents/carers should set a reminder for several weeks before the AAI is due to expire or they register for an expiry alert service (offered on the manufacturers website: Epipen® OR Jext®), to make sure that there is enough time to obtain a prescription for a new AAI device
- Please remind patients/parents/carers that the journey to and from school still requires access to an AAI and there have been many cases of reactions during that timeframe

For the schools who have pupils with allergies:

- Schools have a legal duty to make arrangements for the safety of pupils with medical conditions (including those with food allergies) while in their care. They are encouraged to consider purchasing "spare" AAIs as part of this
- Schools that have "spare/back-up" AAIs in the event of a child's anaphylaxis can ADMINISTER the SPARE AAI when advised by emergency services (e.g. 999 or NHS 111 call) or if permission has been given by the family this permission is part of every allergy management plan

Prescribing Guidance in Primary Care for Adrenaline Auto-Injectors (AAIs)

A. INTRODUCTION

Anaphylaxis is a severe, potentially life-threatening, generalised or systemic hypersensitivity reaction which is likely for both adults and children when both of the following criteria^{1A} are met:

- 1. Sudden onset and rapid progression of symptoms
- 2. Compromise of the airway, breathing and/or circulation systems

Skin and/or mucosal changes (flushing, urticaria, angioedema) can also occur but are absent in a around 10% of cases and if not present do not exclude a diagnosis of anaphylaxis.

Anaphylaxis is a clinical diagnosis either acutely during an episode or retrospectively based on the history provided to the clinician.

To harmonise practices across North-East London and to align with the national guidance and perceived ambiguity around the quantity of AAIs to be prescribed, the following has been recommended:

- 2 AAIs are always available to the patient at all times
- For school age children an additional TWO AAI's can be held on school premises for the purposes of safety and access to AAIs

A separate but complementary document has been drawn up for Frequently Asked Questions (FAQs) for parents and schools which can be used by health professionals as material to support them answering any questions regarding this topic.

It is recommended that that this guidance be used in conjunction with the latest national guidelines where applicable.

Below is a table to aid awareness of the signs and symptoms of anaphylaxis, additionally this an online resource for parents/carers:

https://www.bbc.co.uk/programmes/articles/3Xwcf1ndsPD4GWXM3RXKMHx/how-do-i-treat-someone-having-an-allergic-reaction

Airway problems Circulation problems: Breathing problems: Airway swelling Increased work of Signs of shock: (throat and tongue breathing pale, clammy swelling causing difficulty Bronchospasm (wheeze) in breathing/swallowing; significant tachycardia and/or persistent cough (increased heart rate) patients may feel their Patient becoming tired throat is closing) hypotension with the effort of breathing (low blood pressure) Hoarse voice (fatigue) · Dizziness, decreased Stridor (a high-pitched Hypoxaemia inspiratory noise caused conscious level or loss of (SpO 2 <94%) which may by upper airway consciousness cause confusion and/or obstruction) Arrhythmia central cyanosis Cardiac arrest Respiratory arrest

	Food	Medication / iatrogenic	Venom from sting or bite (e.g. insect)
Age distribution: anaphylaxis (all severity)	Most common in preschool children, less common in older adults	Predominantly older ages	All ages
Typical presentation	Breathing problems	Circulation problems (breathing problems less common)	Circulation problems (breathing problems less common)
Onset	Less rapid	Rapid	Rapid
History of asthma/atopy	Common	Uncommon	Uncommon

Table 2. Differences in the presentation of anaphylaxis by trigger³⁹

	=	
	Faint	Anaphylaxis
Onset	Over seconds	Over minutes to hours
Resolution	Usually rapid on lying flat, without additional treatment	Over minutes to hours
<u>A</u> irway		
-Airway swelling	٦	٦
-Hoarseness -Stridor	Absent	May be present
Breathing		
-Respiration	Shallow, not laboured	Increased respiratory rate and/or work of breathing
-Wheeze /		
persistent cough	Absent	May be present
Circulation		
-Heart rate	Usually slow, rarely normal	Tachycardia common (but alone does not indicate anaphylaxis)
-Pulse	Central pulse usually palpable	Low-volume central pulse
-Blood pressure	Usually transiently low	Persistent hypotension
D isability		
-Consciousness	Dizziness, transient loss of consciousness - improved by lying flat	Dizziness, loss of consciousness persistent despite lying flat
Exposure (skin)	Often pale/clammy	Flushed, itchy, urticaria/hives, angioedema

Table 3: Typical features which may help distinguish between a vasovagal episode and anaphylaxis. Note that patients may not have all of these features.

From Resuscitation Council guideline for the management of anaphylaxis

B. AIMS AND PRINCIPLES

B1. Guidance Aims

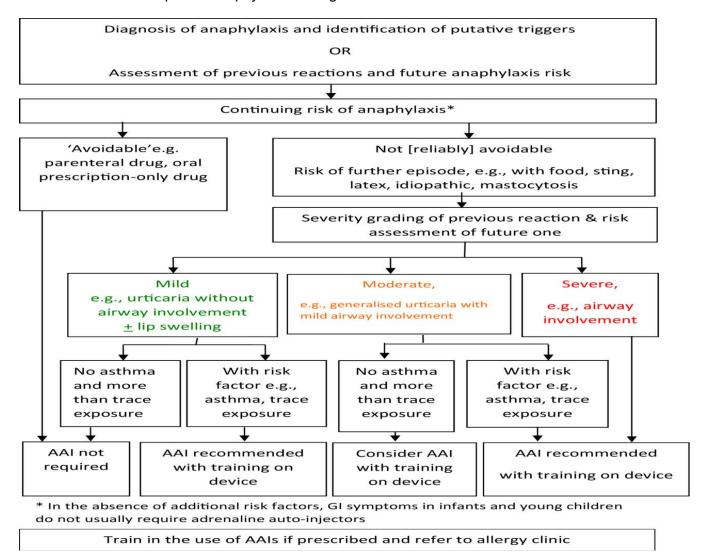
- To co-ordinate work with regional tertiary and local secondary allergy services secondary care, as well as Local Authorities (LAs) responsible for schools to develop a comprehensive NEL ICS wide prescribing policy for AAIs
- To produce guidance for Primary Care prescribers, schools and parents+/guardians across NEL
- To hold a campaign to increase patient knowledge on the AAI usage, storage and their anaphylaxis allergy plan

B2. Guidance Principles

- AAI devices should ONLY be prescribed for a person with a history or an acknowledged clinician assessed risk of an anaphylactic reaction – this includes while waiting for an allergy appointment to investigate for allergies
- All patients should have <u>two AAI devices</u> prescribed, which they should always carry
- AAIs should be prescribed by brand name only as devices and administration instructions may vary
- In children there are different doses of AAIs. The dose is prescribed according to the <u>patient's</u> <u>body weight</u> and not age and there are different brands. In adults there is currently only one dose but different brands that are administered differently

The Royal College of Paediatrics and Child Health <u>Anaphylaxis Working Group</u>^{1A} (AWG) identified four key recommendations from the evidence base:

- 1. Prompt administration of adrenaline by intramuscular injection is the cornerstone of therapy both in the hospital and in the community
- 2. Children and young people at risk of anaphylaxis should be referred to clinics with specialist competence in paediatric allergies
- 3. Risk analysis should be performed for all patients with suspected anaphylaxis this does not need to be by allergists alone and there are algorithms to help with decision making
- 4. Provision of an allergy plan² may reduce the frequency and severity of further reactions and is a recommended part of anaphylaxis management



Angier, E., Choudhury, D., Luyt, D., Baker, S., Warner, A., Clark, A. and Ewan, P. (2023), Adrenaline auto-injector prescription for patients at risk of anaphylaxis: BSACI guidance for primary care. Clin Exp Allergy, 53: 951-954. https://doi.org/10.1111/cea.14325

C. Prescribing Guidance

C1. In acute medical setting after emergency treatment for suspected anaphylaxis¹

- Two AAIs should be prescribed in the Emergency Department /Primary Care/Urgent Treatment Centre with appropriate advice before the patient is sent home
- Before leaving the acute setting the patient/parent/carer needs to be shown by a health professional how to use the prescribed AAI
 - NOTE both Jext[®] and Epipen[®] manufacturers can provide free trainer devices for health professionals to use for teaching purposes
- This is an interim measure in case of another reaction prior to a specialist allergy appointment occurs and is in line with NICE guidance
- After emergency treatment for suspected anaphylaxis, a patient should be referred to a specialist
 allergy service (age-appropriate where possible) consisting of healthcare professionals with the
 skills and competencies necessary to accurately investigate, diagnose, monitor and provide ongoing
 management of, and patient education about, suspected anaphylaxis.

C2. Primary Care setting

- In cases where a previous episode of anaphylaxis is suspected, or it is judged on risk
 assessment that the patient is a notable risk of anaphylaxis then AAIs can be initiated by any
 healthcare prescribing professional
- As mentioned above for children, the AAI dosage should be based on the patient's weight (see below for AAI product information). The child's weight may be ascertained either by routine checks performed at the surgery by a health care professional or by calling the parent/carer
- Ongoing prescriptions for AAIs should follow the Primary Care practice's preferred method, which may include prescribing them as "acute" or "variable repeats"
- The practice must ensure that any AAI requests within a patient's medication records are
 promptly escalated when needed, especially if the prescription is categorized as "acutes".
 For AAIs listed as "variable repeats", it is crucial to regularly review requests to assess the
 ongoing need, considering factors like expiry or usage
- Please refer to Appendix 1 for instructions on placing medications on variable repeats in Emis and TPP SystmOne
- Until a child with allergies is > 25 kg above this weight the AAI dose can only be 300 micrograms then at each annual repeat prescription the weight should be re-checked. This can either be done as direct measurement or ask the family/carers to weigh at home and inform the practice before the prescription can be issued. Please see section C2A for further information regarding dosing
- Although removal of AAIs based on changing medical need is the province of allergists it is
 worth checking when speaking to patients/family/carers if the AAI has been discontinued in
 case there has been a failure in communication to Primary Care This approach is to ensures
 regular reviews, particularly when the AAI dosage is weight dependent
- Patients should receive an anaphylaxis allergy plan³, available on the Ardens AAI template in EMIS under Clinical Effectiveness, or from the British Society for Allergy and Clinical Immunology (BSACI) allergy action plan (available for adults and children, with different AAI

brands and there is a version for cases of allergy where no AAI is needed). Clinicians should review the allergy action plan each time a new AAI prescription is requested. If there are no changes to the diagnosis or management, the medical information in the action plan does not need to be updated, but the record should reflect that the plan has been reviewed, and no changes are necessary. If the patient is a child, advise the family that the photograph affixed to the plan should be updated for easy identification

- If it is necessary to switch to a different brand of AAI⁴ (e.g., due to supply issues), it is crucial that the patient and their caregivers are trained on how to use the new autoinjector, as different brands may be used differently. An updated allergy plan for the new autoinjector pen should also be provided as mentioned above different versions of the plan are available depending on the brand
- <u>Disposal of used AAIs</u>: used AAIs can be given to the ambulance paramedics on arrival or can be disposed of in a sharps bin which can be prescribed. Local councils are responsible for collecting and disposing of clinical waste, please click <u>here</u> for more information. For free collection of sharps bin within Barking and Dagenham, City and Hackney, Havering, Redbridge, please contact: 03301 224220

Provide the following guidance to patients and caregivers:

- Always carry two in-date AAIs^{5,6}
- Ensure that individuals with allergies⁴ and their caregivers are trained on how to use the specific auto-injector prescribed to them
- Encourage individuals with allergies and their caregivers to obtain and practice using a training device for Epipen® or Jext®8 via the manufacturers' website
- All AAIs have an expiry date. Advise parents and caregivers to monitor these dates and set a
 reminder or register for an expiry alert service (available on the manufacturer's website for Epipen^{®7}
 or Jext^{®8}) several weeks in advance. This ensures enough time to obtain a prescription for a new
 device⁹. If parents need a new AAI outside normal surgery hours, they should call 111, where the
 operator can direct them to the appropriate pharmacy for an in-date AAI
- AAIs should be administered immediately if anaphylaxis is suspected, even if there is uncertainty about the severity
- Symptoms of anaphylaxis may include throat or tongue swelling, wheezing or difficulty breathing, dizziness, fatigue, and confusion.
- After administering adrenaline, dial 999 to request emergency medical assistance, and inform the operator that it is an anaphylaxis situation ("ana-fill-axis").
- If there is no improvement after 5 minutes, use your second AAI in the opposite thigh to the one already injected
- Consider subscribing to the MedicAlert Foundation, a registered charity providing life-saving identification for individuals with hidden medical conditions and allergies. This system includes body-worn bracelets or necklets (MedicAlert Emblems) with the MedicAlert symbol, supported by a 24-hour emergency telephone service^{9A}

Recognition and management of an allergic reaction/anaphylaxis

Signs and symptoms include:

Mild-moderate allergic reaction:

- Swollen lips, face or eyes Abdominal pain or vomiting
- Itchy/tingling mouth Sudden changein
- Hives or itchy skin rash

ACTION:

- Stay with the child, callforhelp if necessary
- Locate adrenaline autoinjector(s)
- Give antihistamine according to the child's allergy treatment plan
- Phone parent/emergency contact



Watch for signs of ANAPHYLAXIS (life-threatening allergic reaction):

AIRWAY: Persistent cough

Hoarse voice

Difficulty swallowing, swollen tongue

behaviour

BREATHING: Difficult or noisy breathing

Wheeze or persistent cough

CONSCIOUSNESS: Persistent dizziness

Becoming pale or floppy

Suddenly sleepy, collapse, unconscious

IF ANY ONE (or more) of these signs are present:

 Lie child flat with legs raised: (if breathing is difficult, allow child to sit)







- 2. Use Adrenaline autoinjector* without delay
- Dial 999 to request ambulance and say ANAPHYLAXIS

*** IF IN DOUBT, GIVE ADRENALINE ***

After giving Adrenaline:

- 1. Stay with child until ambulance arrives, do NOT stand child up
- Commence CPR if there are no signs of life
- Phone parent/emergency contact
- If no improvement after 5 minutes, give a further dose of adrenaline using another autoinjector device, if available.

Anaphylaxis may occur without initial mild signs: ALWAYS use adrenaline autoinjector FIRST in someone with known food allergy who has SUDDEN BREATHING DIFFICULTY (persistent cough, hoarse voice, wheeze) – even if no skin symptoms are present.

*: In school with "spare" back up AAI, administer the AAI where available

C2A: AAI product information:

- Always prescribe by brand: EpiPen® OR Jext®
- Dosing must always be <u>adjusted to the weight of patient</u>. Ensure this is reviewed before issuing a prescription. Patients with a weight of >60kg were in the past signposted to Emerade® 500microgram. As this product was <u>recalled</u>¹⁰ in 2019 due to safety risks guidance has now changed and patients with a weight of >60kg will require a dose of 300-500microgram. Although Epipen® and Jext® are available in a maximum strength of 300 microgram, these AAIs deliver more adrenaline, as a proportion of dose, to the bloodstream in the first 30 minutes following injection, compared with Emerade® 500 microgram. Therefore, the development of a 500-microgram strength for all AAIs cannot be recommended at present. <u>Patients</u>¹¹ can be reassured that a single Epipen® or Jext® 300 microgram AAI is a suitable replacement for an Emerade® 500 microgram AAI
- Following a review of dosing of adrenaline/epinephrine auto-injector devices for acute anaphylaxis, the body-weight ranges for Jext® have been aligned with those of EpiPen® so that all children weighing 25kg and over may be given a dose of 300 micrograms. Currently Jext® is licensed to be given at a dose of 150 micrograms for those between 15kg and 30kg in weight. The review of dosing found that guidelines supported dose transition to 300 micrograms at a body weight of 25kg, and the ranges in the BNF²³ have therefore been aligned. While prescribing the higher 300 microgram dose in this age and weight range is considered unlicensed, it may be clinically appropriate in certain circumstances based on individual risk assessment. GPs may initiate the 300-microgram dose where justified but should be aware of its unlicensed use. If further guidance is required, GPs are encouraged to use the "Advice and Guidance" service to contact the local Specialist Allergy Clinic for patient-specific recommendations.

Product name	Dose by weight kilogram(kg)	Patient information leaflet	Educational material producedby the manufacturer	Free trainer pens available
EpiPen® Jr. 0.15 mg adrenaline (epinephrine) auto-injector Viewing window Blue safety cap Orange tip	Child from <mark>7.5 – 25kg</mark> – 0.15mg dosage (Green Label)	EpiPenJr ^{®12} auto- injectors	EpiPen® Jr <u>user</u> <u>guide and</u> <u>instruction</u> <u>video</u> ¹³	Yes: EpiPen® Training Pen EpiPen® ⁷
EpiPen® 0.3 mg and adrenaline (epinephrine) auto-injector Viewing window Blue safety cap Orange tip	Adult and children <mark>over 25kg</mark> – 0.3mg dosage (Yellow Label)	EpiPen ^{®14} auto- injectors	EpiPen® <u>user</u> <u>guide and</u> <u>instruction video</u> ¹⁵	Yes: EpiPen® Training Pen EpiPen® ⁷

Jext® 150 micrograms solution for injection in prefilled pen	Children between 15kg and 30kg (Yellow label)	<u>Jext</u> [®] <u>pre-</u> <u>filled pens</u> ¹⁶	Jext® <u>user</u> guide and instruction video ¹⁷	Yes: <u>Order</u> <u>Literature</u> ¹⁸
Jext® 300 micrograms solution for injection in pre- filled pen	Adults and Children <mark>over</mark> <mark>30kg</mark> (Red label)	<u>Jext[®] pre-</u> filled pens ¹⁶	Jext [®] <u>user</u> <u>guide</u> and <u>instruction</u> <u>video</u> ¹⁷	Yes: <u>Order</u> <u>Literature</u> ¹⁸

C3. How many AAIs should be prescribed?

The <u>longstanding regulatory advice</u>¹⁹ is that patients should be prescribed **TWO** AAIs to support the effective and safe use of adrenaline auto-injectors as the norm, and that the patient should always have immediate access.

For primary school children:

Issue no more than <u>2 AAIs per patient</u> **BUT** exceptions suggested to this in a 2019 DHSC supply disruption alert are:

• where schools require separate AAI(s) to be kept on the school premises (e.g. in a medical room) in which case prescribers may need to consider issuing more than 2 but no more than 4 AAIs per child.

Parents should be reminded that their child should always have access to the AAIs even on the way to and from school: This recommendation proves to be a challenge today as several technical and practical challenges exist including a short shelf-life (time to expiry) of up to 18 months means that it is not uncommon for AAIs reaching patient to have around 15 months or less to expiry. In addition, there have also been national shortages that resulted in curtailment of prescribing quantities that resulted in only 2 AAIs per patient.

For secondary school children and adults:

The MHRA²⁰ recommend that 2 AAIs are prescribed, which patients should always carry and are trained to self-administer though this will depend on the individual's maturity and readiness. If necessary, they can have the AAI administered by trained staff²¹

A recommendation that the school, the patient and the parents/carers have a meeting to discuss suitability of the young person carrying his/her own devices at school – as this is not a specific medical decision

For any other setting:

Requests for more than two (four, for a child where applicable as stated above) AAIs should be discouraged. The overriding principle is that the patient should always be carrying the AAIs, rather than having them at multiple locations which might not always be accessible.

D. Resources for the safe use of AAIs:

On 19 June 2023, the MHRA, with the support of allergy awareness advocates, has launched a safety campaign to raise awareness of anaphylaxis and provide advice on the use of adrenaline auto-injectors (AAIs). The launch coincides with the World Allergy Week, an annual initiative led by the World Allergy Organization.

A toolkit of resources is now available for health and social care professionals to support the safe and effective use of AAIs.

The resources are freely available for download from the MHRA's quidance page 20 on AAIs and include:

- infographic about the correct use of your AAI see Welsh version
- videos about the correct use of your AAI: https://youtu.be/4vNR5N1-iBw²²

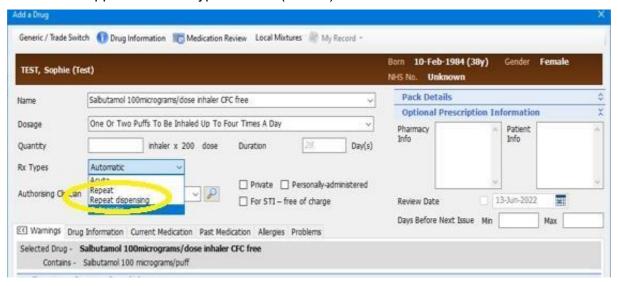
Appendix 1: How to Add a Variable Use Repeat Medication on EMIS Web

Variable Use Repeat Medication is a function which allows you to add medication that is being used on a when necessary (PRN) basis.

To avoid the prescribing of repeat items that are 'when required' or of variable use (such as some inhalers/cream etc.) being issued every month unnecessarily along with the regular repeat items, this feature quickly and easily separates them off from regular repeat or repeat dispensing medicines on the medication screen.

Steps:

- 1. Select 'Add Drug'
- 2. Enter medication details as usual
- 3. From the drop-down list select Rx type as 'Repeat' or 'Repeat Dispensing'. The Variable Use check box is only available if Rx type is repeat/repeat dispensing. It will not appear if the Rx type is acute (default)



4. Select the Variable Use box

5. Select issue later or issue where appropriate Generic / Trade Switch 1 Drug Information Medication Review Local Mixtures My Record v Born 10-Feb-1984 (38y) Gender Female TEST, Sophie (Test) NHS No. Unknown **Pack Details** Salbutamol 100micrograms/dose inhaler CFC free Name **Optional Prescription Information** One Or Two Puffs To Be Inhaled Up To Four Times A Day Dosage Pharmacy Patient Day(s) Quantity inhaler x 200 dose Duration Rx Types Repeat Authorised Issues Privata Personally-administered

6. Once complete the medication will appear in a separate box on the patient's record as shown below

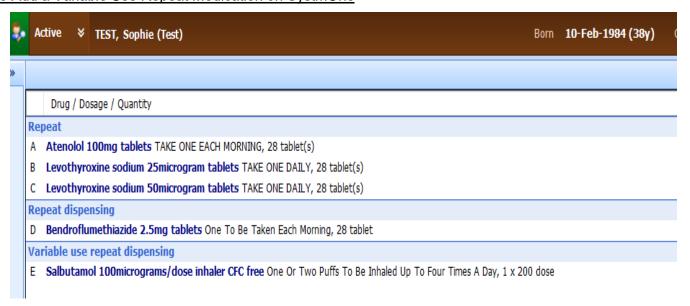
For SII – free of charge

☐ Variable use

How to Add a Variable Use Repeat Medication on SystmOne

(C) Warnings Drug Information Current Medication Past Medication Allergies Problems

Authorising Clinician KASHYAP, K P (Dr)



13-Jun-2022

Review Date

Days Before Next Issue Min

Max

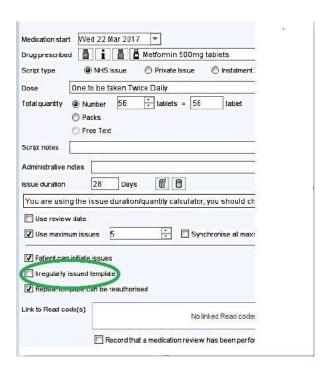
Variable Use Repeat Medication is a function which allows you to add medication that is being used on a when necessary (PRN) basis.

To avoid the prescribing of repeat items that are 'when required' or of variable use (such as some inhalers/cream etc) being issued every month unnecessarily along with the regular repeat items, this feature quickly and easily separates them off from regular repeat or repeat dispensing medicines on the medication screen.

Steps:

- 1. Select 'Drug Prescribed'
- 2. Enter repeat medication details as usual

3. Tick the box 'Irregularly issued template'. This check box is only available if Rx type is repeat/repeat dispensing. It will not appear if the Rx type is acute (default).



Appendix 2: FAQs for Health Care Professionals (HCPs)

- 1. How many AAIs should I prescribe for a child <12years of age? Issue no more than 2 AAIs per patient BUT exceptions suggested to this in a 2019 DHSC supply disruption alert are where schools require separate AAI(s) to be kept on the school premises (e.g. in a medical room) in which case prescribers may need to consider issuing more than 2 but no more than 4 AAIs per child
- 2. **How do I manage AAI supply issues**? Ascertain clinically how many AAI devices are required and prescribe the alternate brand. Additionally, signpost the parent/carer on how to use the new AAI device effectively as the AAI devices are not interchangeable
- 3. How often does the anaphylaxis allergy plan get updated? Clinicians should review the allergy action plan <u>each time</u> a new AAI prescription is requested. If there are no changes to the diagnosis or management, the medical information in the action plan does not need to be updated, but the record should reflect that the plan has been reviewed, and no changes are necessary. If the patient is a child, advise the family that the photograph affixed to the plan should be updated for easy identification
- 4. What dose do I prescribe? the AAI dosage should be based on the patient's weight (see section C2A for AAI product information)
- 5. How do I manage repeat requests of the AAI devices? any AAI requests within a patient's medication records are promptly escalated when needed, especially if the prescription is categorized as "acutes". For AAIs listed as "variable repeats", it is

crucial to regularly review requests to assess the ongoing need, considering factors like expiry or usage (See Appendix 1 on how to place medications on variable repeats)

- 6. What resources do I give to my patient to manage the expiration of the AAI device and training:
- Viatris Connect. EpiPen trainer pen registration. Viatris Connect.
 https://cloud.email.viatrisconnect.com/EpiPen-Trainer-Pen-Registration
- * ALK-Abelló Ltd. (2023). Order Jext® trainer pen. https://kids.jext.co.uk/order-jext-trainer-pen/
- MHRA's guidance page
- videos about the correct use of your AAI: https://youtu.be/4vNR5N1-iBw
- Parent/carer also needs to manage expired AAI devices left at school or any other caregiving facility

Checklist for re-authorisation of AAIs:

- If carrying out a telephone consultation, request the child's current body weight or else weigh the child at the surgery
- Check the parents/carers understanding of the signs and symptoms of anaphylaxis and reenforce key messages
- Can the parent/carer demonstrate working knowledge of the AAI?
- Confirm that the parent/carer has signed up to receive expiry reminders for the AAIs from the respective manufacturer or have a robust system to monitor expiry dates of the AAI devices
- Signpost parents/carers to online resources

References:

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