North East London
Integrated Care Board

**Barts Health NHS Trust**
**Homerton Healthcare NHS Foundation Trust**
**Barking, Havering and Redbridge University Hospitals NHS Trust**
**East London NHS Foundation Trust**
**North East London NHS Foundation Trust**

# North East London Integrated Care Board (NEL ICB)

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

| Document Control | |
|---|---|
| **This policy will impact on:** | NHS North East London clinicians |
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## Contents



**SUMMARY**

**For Primary Care health professionals**:

- 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 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*

# NEL ICB: 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.

| Airway problems | Breathing problems: | Circulation problems: |
|---|---|---|
| • Airway swelling (throat and tongue swelling causing difficulty in breathing/swallowing; patients may feel their throat is closing)<br>• Hoarse voice<br>• Stridor (a high-pitched inspiratory noise caused by upper airway obstruction) | • Increased work of breathing<br>• Bronchospasm (wheeze) and/or persistent cough<br>• Patient becoming tired with the effort of breathing (fatigue)<br>• Hypoxaemia ($SpO_2$ <94%) which may cause confusion and/or central cyanosis<br>• Respiratory arrest | • Signs of shock:<br>  ○ pale, clammy<br>  ○ significant tachycardia (increased heart rate)<br>  ○ hypotension (low blood pressure)<br>• Dizziness, decreased conscious level or loss of consciousness<br>• Arrhythmia<br>• Cardiac 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 trigger**[39]

| | Faint | Anaphylaxis |
|---|---|---|
| Onset | Over seconds | Over minutes to hours |
| Resolution | Usually rapid on lying flat, without additional treatment | Over minutes to hours |
| **A**irway | | |
| -Airway swelling<br>-Hoarseness<br>-Stridor | Absent | May be present |
| **B**reathing | | |
| -Respiration | Shallow, not laboured | Increased respiratory rate and/or work of breathing |
| -Wheeze / persistent cough | Absent | May be present |
| **C**irculation | | |
| -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<br>- improved by lying flat | Dizziness, loss of consciousness persistent despite lying flat |
| **E**xposure (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

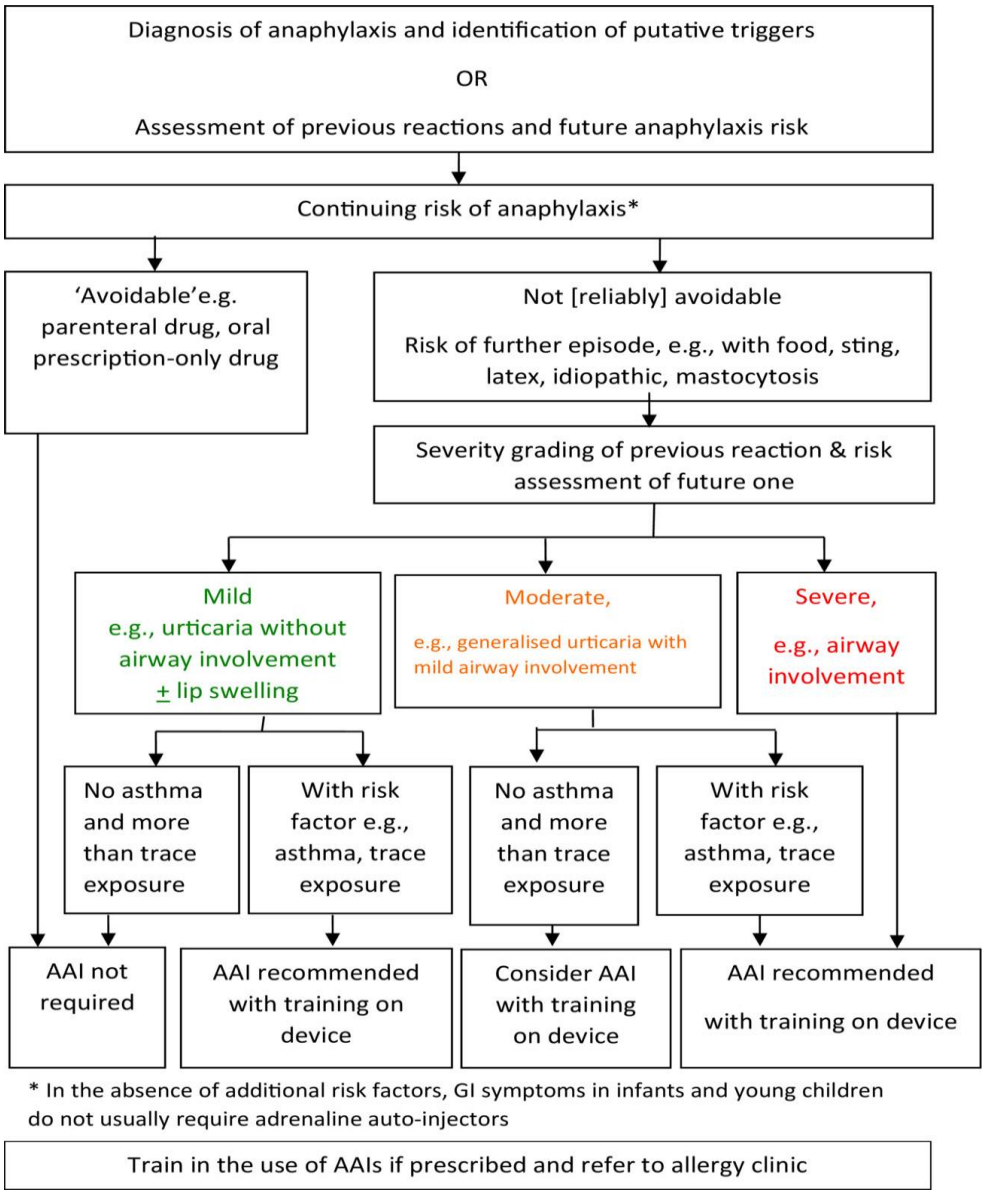
- To co-ordinate work with regional tertiary and local secondary allergy services secondary care, as well as Local Authorities (LAs) responsible for schools to develop a comprehensive NEL ICS wide prescribing policy for AAIs
- To produce guidance for Primary Care prescribers, schools and parents+/guardians 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 **two AAI devices** 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 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 Royal College of Paediatrics and Child Health Anaphylaxis Working Group[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 plan[2] 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 anaphylaxis[1]

- 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 SystemOne
    - 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.
    - Although removal of AAIs based on changing medical need is the province of allergists (who are happy to be consulted with any queries from Primary Care) 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 plan[3], 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 AAI[4] (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.

Provide the following guidance to patients and caregivers:

- Always carry two in-date AAIs[5,6]
- Ensure that individuals with allergies[4] 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 device[9]. 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
- Itchy/tingling mouth
- Hives or itchy skin rash
- Abdominal pain or vomiting
- Sudden change in behaviour

ACTION:

- Stay with the child, call for help 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<br>Hoarse voice<br>Difficulty swallowing, swollen tongue |
| BREATHING: | Difficult or noisy breathing<br>Wheeze or persistent cough |
| CONSCIOUSNESS: | Persistent dizziness<br>Becoming pale or floppy<br>Suddenly sleepy, collapse, unconscious |

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

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

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

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

After giving Adrenaline:

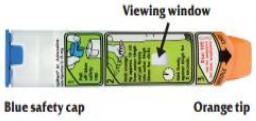
1. Stay with child until ambulance arrives, do NOT stand child up
2. Commence CPR if there are no signs of life
3. Phone parent/emergency contact
4. If no improvement after 5 minutes, give a further dose of adrenaline using another autoinjector device, if available.

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*
- *Dosing must always be **adjusted to the weight of patient**. 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 recalled[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. Patients[11] can be reassured that a single Epipen® or Jext® 300 microgram AAI is a suitable replacement for an Emerade® 500 microgram AAI*

| 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   | Child from **7.5 – 25kg** – 0.15mg dosage (Green Label) | EpiPenJr®[12] auto-injectors | EpiPen® Jr user guide and instruction video[13] | Yes: EpiPen® Training Pen \| EpiPen®[7] |
| EpiPen® 0.3 mg and adrenaline (epinephrine) auto-injector   | Adult and children **over 25kg** – 0.3mg dosage (Yellow Label) | EpiPen®[14] auto-injectors | EpiPen® user guide and instruction video[15] | Yes: EpiPen® Training Pen \| EpiPen®[7] |
| Jext® 150 micrograms solution for injection in pre-filled pen  | Children between **15kg and 30kg** (Yellow label) | Jext® pre-filled pens[16] | Jext® user guide and instruction video[17] | Yes: Order Literature[18] |
| Jext® 300 micrograms solutionfor injection in pre- filled pen  | Adults and Children **over 30kg** (Red label) | Jext® pre-filled pens[16] | Jext® user guide and instruction video[17] | Yes: Order Literature[18] |

### C3. How many AAIs should be prescribed?

The longstanding regulatory advice[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 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.

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 MHRA[20] recommend that 2 adrenaline auto-injectors 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 staff[21]

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 guidance 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-iBw[22]

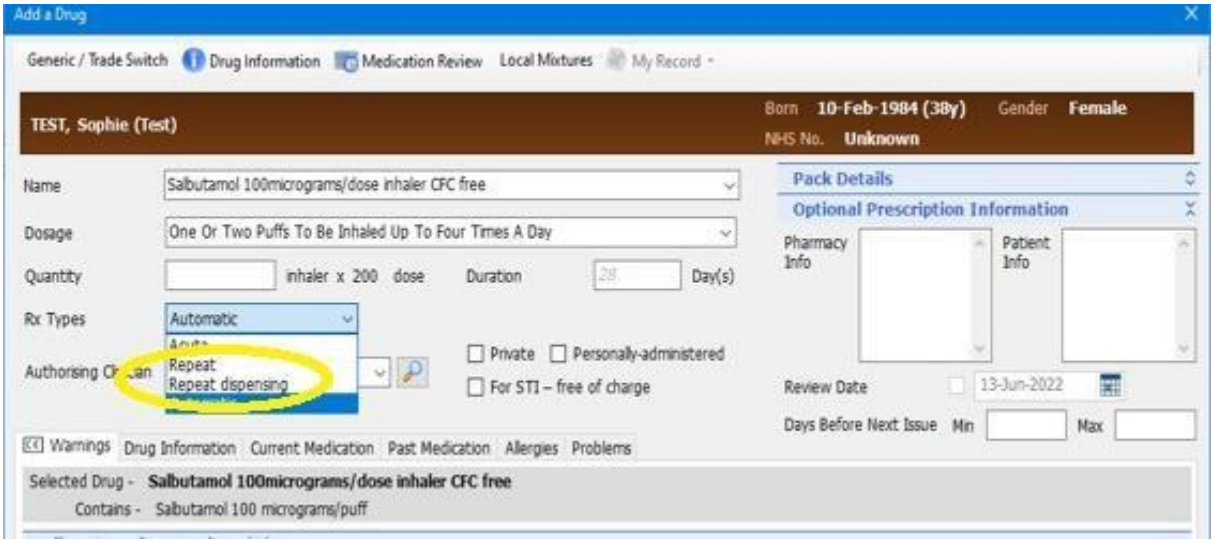
Appendix 1: **How to Add a Variable Use Repeat Medication on EMIS Web**

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

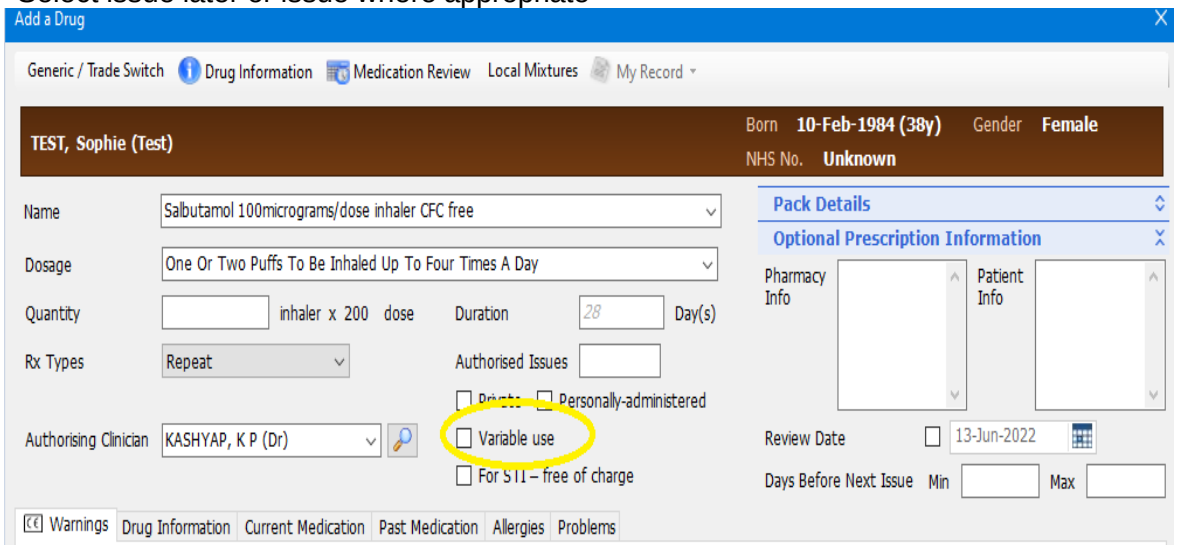
To avoid the prescribing of repeat items that are 'when required' or of variable use (such as some inhalers/cream etc.) being issued every month unnecessarily along with the regular repeat items, this feature quickly and easily separates them off from regular repeat or repeat dispensing medicines on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




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

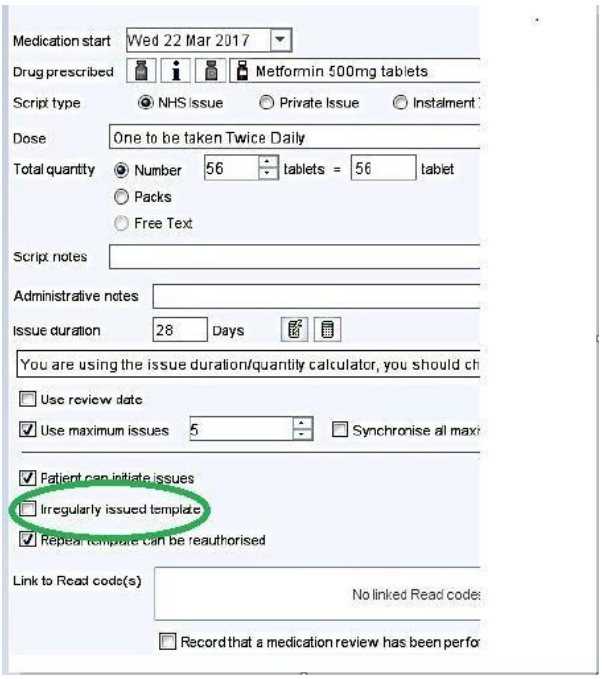

## How to Add a Variable Use Repeat Medication on SystemOne

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).



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