

Use of pre-filled IV elastomeric pumps (Baxter Infusor LV10 device) within the BNSSG NHS@Home Outpatient Antimicrobial Therapy (OPAT) service.

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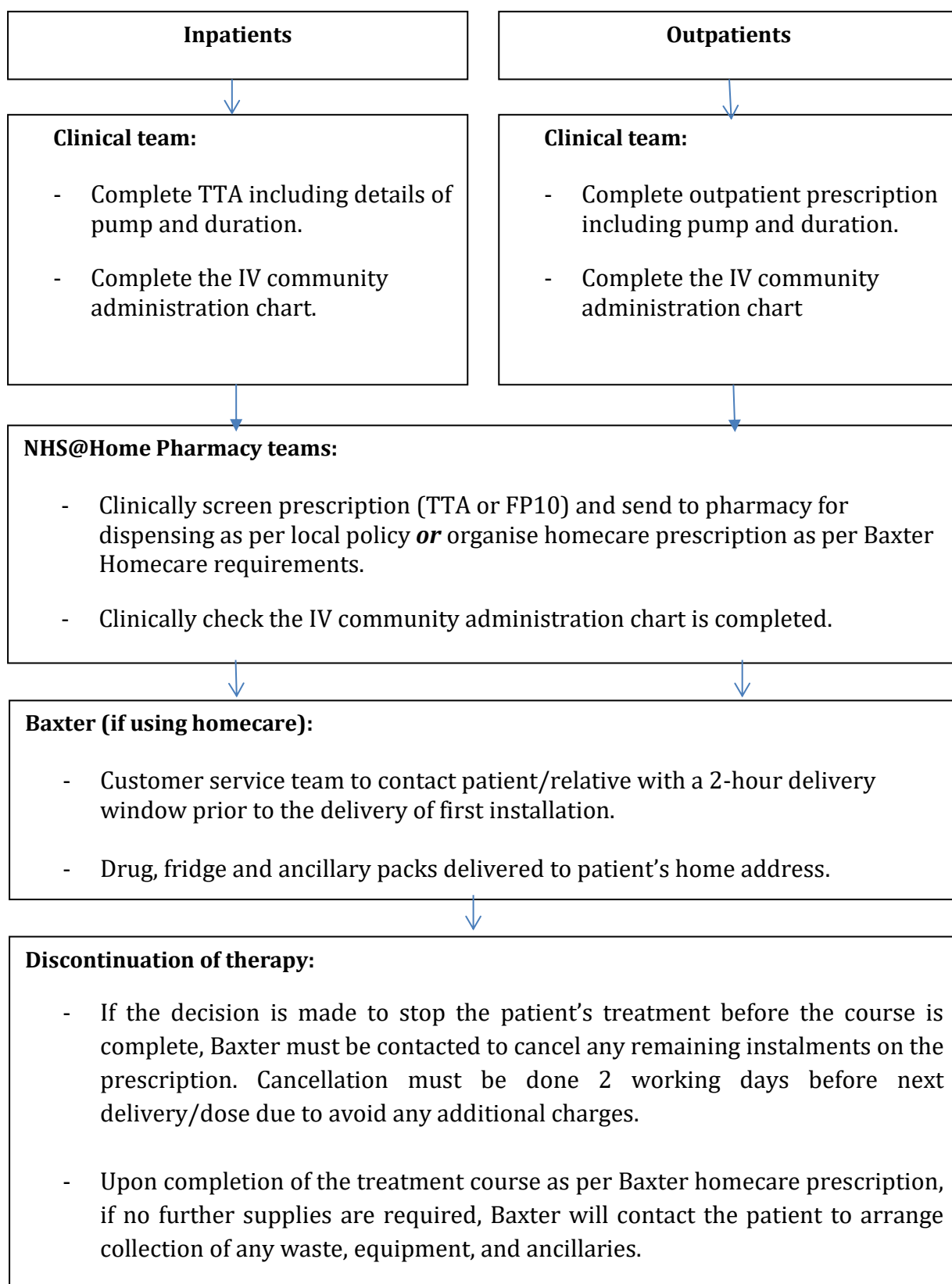
1. Introduction

The NHS@Home OPAT service facilitates early discharge from hospital or prevents hospital admission. The Baxter LV10 Infusor is a disposable, single use, elastomeric infusion system which can administer IV medications as a 24-hour continuous infusion. This reduces the requirement for multiple times a day nursing visits for administration making it a viable method of delivery for the OPAT service. The pumps are portable and light weight, allowing treatment flexibility and are suitable for home settings. The pumps are aseptically compounded and are classed as an unlicensed product.

2. Clinical indication and patient suitability

- All IV antibiotic treatment via Baxter LV10 for OPAT patients must be approved an infections specialist, as per OPAT policy.
- Once identified by an infections specialist, the patient will be assessed by the OPAT team for service suitability, as per OPAT policy.
- In addition, the patient will be assessed for the Baxter LV10 pump, using the assessment proforma (Appendix 1). The patient will sign the proforma, consenting to receive an unlicensed treatment.

3. Prescribing and supplying



4. Administration

- When using a Baxter LV10 Infusor, the vascular access device should be 22 gauge or larger to achieve an adequate flow rate. For the administration of all Baxter LV10 infusions, a Peripherally Inserted Central Catheter (PICC) will be required.
- Use Aseptic Non-Touch Technique (ANTT) throughout the procedure.
- Description of the Baxter LV10 Infusor is given in Appendix 3.
- See Appendix 4 for Guide to connecting and exchanging the Baxter LV10 Infusor.
- The staff required for the first visit will be determined by the completion of the NHS@Home anaphylaxis risk assessment.

5. Record keeping and documentation

- Administration records must be recorded on the authorisation to administer record
- A record of an elastomeric pump being administered should also be made on a patient's electronic patient record (i.e. EMIS)
- The batch number and expiry date of the elastomeric device should be recorded on the "Record of Drug Administration" chart to allow for traceability.

6.1 Storage when using Baxter Homecare

- Baxter will deliver a fridge to the patient's nominated address at the point of medicine delivery.
- Fridge dimensions: 735mm x 450mm x 510mm
- The fridge has an inbuilt thermometer and an alarm and will sound if it goes out of range (2-8°C). The patient will be given an information leaflet from Baxter on first delivery of medicines which will provide contact details to call in the event of a fridge alarming (Baxter 24-hour helpline: 08000288966 or 01727849720 also see Appendix 5). In the eventuality of an out-of-range temperature deviation, Baxter will guide the patient on actions to take. If the stock at patient's home can no longer be used, Baxter will inform NBT Homecare team/UHBW nursing team and arrangement will be in place to ensure continuation of treatment is ensured.
- It is the responsibility of the Health Care Professional attending to administer medication via elastomeric devices to check the maximum and minimum temperature readings for the last 24 hours and record this on the monitoring form provided (Appendix 6). If there have been any temperature excursions outside of 2-8°C, Baxter must be notified immediately.
- In the event that the medication is unable to be used – contact the NHS@Home coordinator who will discuss with the NHS@Home pharmacist and infections specialist who will establish an individual management plan for the patient. See section 8 for delivery timeframes. Note supplies are unable to be requested from Baxter over a weekend or Bank Holiday.
- Upon completion of the treatment course, if no further supplies are required, Baxter will contact the patient to arrange collection of the fridge.

6.2 Storage when pumps are being taken out from fridge in NHS@Home office

- If patients are unable to utilise Baxter Homecare, pumps can be ordered to be delivered to the hospital site where they will be stored until they are needed for administration.

- These pumps are stored in a medicine's fridge in the NHS@Home office as per local fridge storage guidelines. Daily temperature checks are performed on these fridges to ensure cold chain storage is maintained.
- The LV10 elastomeric pumps are stable at room temperature for three hours. The pumps can therefore be removed from the fridge, transported to a patient's house and connected within three hours from the time they were taken out of the fridge, as detailed by stability data provided by Baxter.

7. Disposal of waste

- If homecare is being used, A large sharps bin is provided by Baxter when the first delivery is made. All used elastomeric pumps should be disposed of in this bin. Upon completion of the treatment course, if no further supplies are required, Baxter will contact the patient to arrange collection of any waste, equipment and ancillaries.
- If pumps are being taken out by NHS@Home nursing staff from fridges in NHS@Home team sites, used elastomeric pumps will be disposed of in sharps bins as per local trust policy.

8. Cancellation process

If the decision is made to stop the patient's treatment before the course is complete, the NHS@Home pharmacy team will contact Baxter to cancel any remaining instalments on the prescription. Cancellation must be done 2 working days before next delivery/dose due to avoid any additional charges.

9. Baxter delivery timeframes

Homecare:

Baxter will contact the patient or nominated representative to arrange delivery of the medication and ancillaries (fridge/waste bin)

Standard Delivery: 3pm cut off on day 1 for delivery 8am – 8pm on day 3

Next Day delivery: 1pm cut off on day 1 for delivery 8am – 8pm on day 2 (this has an additional charge).

There is no delivery on Sundays

Order (day 1) (3pm cut off)	Standard delivery (8 - 8pm)
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday
Thursday	Saturday
Friday	Monday

Hospital delivered:

12pm cut off on day 1 for day 3 delivery by 17 00 on day 3.

There is no delivery on Saturdays or Sundays

Order (day 1) (12pm cut off)	Standard delivery (by 5pm)
Monday	Wednesday
Tuesday	Thursday
Wednesday	Friday
Thursday	Monday
Friday	Tuesday

10. Liability and insurance

In the case of damage caused to a patient's property by a Baxter supplied fridge, Baxter holds product liability, public liability and professional indemnity insurance – details of which can be found within the regional contract specifications.

In the case of damage to a Baxter supplied fridge due to the patient's/carer's negligence, misuse or failure to observe any instructions or training concerning the use of the equipment, Baxter have the right to recover the cost of repair or replacement from the Trusts, provided that such negligence, misuse or failure was not caused or contributed to by any action of or failure to take action by Baxter. Further details can be found in the regional contract specifications.

11. Product Stability

- Flucloxacillin: 21 days at 2°C to 8°C
- Piperacillin & tazobactam (Tazocin®) 21 days at 2°C to 8°C
- Benzylpenicillin: 14 days at 2°C to 8°C

The elastomeric pumps are stable for three hours at room temperature, therefore must be connected within three hours of being removed from the fridge.

12. Troubleshooting and Incident Reporting

Trouble shooting – refer to Baxter LV10 Infusor reference guide provided by Baxter (ref UK/35/16-0002c(1) July 2019:



It is important that any fault of the Baxter LV10 Infusor or adverse event is reported to the NHS@Home Team and recorded via Datix incident reporting system. All relevant documentation and equipment must be retained, Pharmacy QA contacted and items returned to the manufacturer for investigation where necessary.

13. Infusion progress monitoring

The infusion progress is carried out by comparing the size of the reservoir with the Baxter LV10 Infusor Progression chart (see Appendix 7). Patient training and education will be provided as part of the assessment process. The patient must contact the OPAT team if the reservoir size does not change with time as per chart.

The Infusion Progression chart can be subjective to interpretation. There is a +/- 10% accuracy with the Baxter LV10 Infusor; the infusion can complete as quickly as 22 hours or a slowly as 26 hours. It is acceptable to change the device at point 7 on the Infusion Progression chart.

Factors that can influence the infusion duration

- **Temperature**

When using a Baxter LV10 Infusor it is important to tape the white distal end luer lock directly on the patient's skin and where the flow restrictor is located. The Baxter LV10 Infusor flow rate is calibrated at 33.3°C. The device must not be placed next to a heat source such as a fire or radiator. The device must be kept in the isothermal pouch provided with the device for the duration of treatment.

- **Head Height**

The Baxter LV10 Infusor flow rates are optimal when the medication reservoir and the distal end luer lock are positioned at the same height as the needle free device. The OPAT nurse administering the treatment is responsible for providing patient education and demonstrating the correct positioning.

14. Training

All Registered Nurses must receive training and supervision on the principles of care and management of a Baxter LV10 Infusor from a recognised core trainer (Level 5) and be deemed as competent (Level 4).

Registered nurses must be able to provide evidence of competency in caring for a Baxter LV10 Infusor (Appendix 8) and it is the responsibility of individual nurse to keep their own documented evidence of competency. Re-assessment of this competency must be undertaken every 3 years.

The following website provides videos, a step by step guide to setting up a Baxter LV10 Infusor and a FAQs section (www.opatwithbaxter.co.uk).

15. Patient advice

The patient will also receive ongoing education, training and support by the OPAT service for the care of a Baxter LV10 Infusor.

Appendix 1

Assessment and Consent for the suitability of patient in the use of Baxter LV10 Infusor at home

Assessment

Is the patient happy to receive this approved but unlicensed treatment? **Yes** **No**

Is there enough space for a fridge (dimension 735mm x 450mm x 510mm)? **Yes** **No**

The patient/patients representative will be present to receive delivery from Baxter within allocated time slot set by Baxter **Yes** **No**

NB. Additional information around unlicensed treatment will be provided by the OPAT Pharmacist.

Is the patient or carer able to follow the Infusor Progression chart and to report the infusion progression to the nurse over the phone? **Yes** **No**

Points to be covered

When using your Baxter LV10 Infusor 24-hour infusion:

- ☐ The infusion line should be kept unobstructed with no kinks or bends in the tubing
- ☐ The white connector must be kept taped directly to your skin to ensure it reaches body temperature
- ☐ Keep your infusor in its pouch, away from direct sunlight and heat sources such as a fire or radiator
- ☐ Avoid excessive exercise
- ☐ Keep your infusor at the same height as the PICC line
- ☐ Do not place your infusor on the floor
- ☐ Do not hang the infusor above your head
- ☐ Do not submerge the infusor or PICC in water and ensure the line is kept dry
- ☐ Look at your infusor every 4 hours while awake and compare against your infusor progress chart.
- ☐ Look out for swelling or pain at the PICC line entry site
- ☐ NBT Vascular access leaflet given
- ☐ Baxter LV10 Infusor Infusion progress chart given
- ☐ Only LV10 Infusor is to be kept in the fridge

Any concerns or questions please contact the OPAT service 0117 4142409 (07.00-18.00)

Initial assessment and advice completed by:

Name:..... Designation:.....

Signature:..... Date:.....

I confirm that I have received, and understand the information listed above and consent to having my treatment administered via the Infusor device

Patient Name:..... Signature.....

Date:.....

Appendix 2

Baxter Homecare Prescription



BRI and
Southmead_BAXTER

Appendix 3

Description of the Baxter LV10 Infusor



Appendix 4

Guide to connecting and exchanging of the Baxter LV10 Infusor

Equipment needed:

- LV10 Infusor and dedicated cool bag
- Clean tray
- Syringe, Blunt needle, label, bung and sodium chloride 0.9% ampule or Prefilled flush (10mls)
- 2% chlorhexidine gluconate in 70% alcohol impregnated swab (e.g. Clinell wipe) x1
- Gloves (non-sterile)
- Clean apron
- Sterile drape (if concerned about contamination risk)
- Tape for flow restrictor

Procedure

This is an aseptic non touch technique (ANTT)

The key parts of ANTT are:

- Tip of syringe
 - Needle Free Device (NFD)
 - Tip of Baxter LV10 Infusor
-
- 1) Perform fridge check, record the maximum and minimum temperature over the last 24 hours on the Fridge Monitoring form given in Appendix 6. If minimum temperature below 2C or maximum temperature is above 8C, do not use the pump and contact the OPAT coordinator
 - 2) Reset the thermometer after taking the readings
 - 3) Retrieve the Baxter LV10 Infusor from the Baxter homecare fridge located in the patient's home
 - 4) Check the Baxter LV10 Infusor against the TTA prescription
 - 5) Complete standard drug checks, including Baxter LV10 Infusor safety checklist

Do not use the Baxter LV10 Infusor if:

- The balloon has burst or is split
- There is any sign of leaking drug
- There is a split or break in the tubing
- The distal Luer cap has been removed or is missing
- The fill port protector cap is missing or has fallen off
- The packaging has been previously opened or damaged

NB. Condensation can form inside the plastic housing; this does not mean the reservoir is leaking. Check for pooling by tilting the infusor on an angle

- 6) Clean hands and don apron
- 7) Clean tray and work surface and leave to air dry.

- 8) Clean hands
- 9) Ensure key parts are not touched during procedure (ANTT), unwind the Infusor tubing, prepare all equipment, open the flush and the 2% Clinell wipe and put in tray
- 10) Clean hands and put on non- sterile gloves.
- 11) Prepare patient.

NB. Place Sterile drape under device if concerned about contamination risk (i.e. working around a stoma, tracheostomy or the environment)

- 12) Clean NFD thoroughly with a 2% Clinell wipe for a timed 30 seconds, opening out the wipe, allowing 30 seconds to dry. Once cleaned do not place NFD down.
- 13) Remove bung from the flush syringe. Continue to hold lumen to stabilise and maintain ANTT of the NFD at all times.
- 14) Firmly push and twist syringe into NFD, ensure syringe remains securely attached.

NB. PICCs, Tunnelled Lines, Central Venous Catheters and TIVADs must be aspirated into catheter lumen/ NFD extension for venous return prior to use to confirm venous placement.

- 15) Administer flush using a brisk, pulsatile, push pause technique in 1 ml increments with positive pressure. Finish and disconnect.
- 16) Remove the blue winged luer lock cap

NB. At this stage the infusion will start. Observe the end of the infusion line for a few seconds to visually confirm this stage.

- 17) Attach the infusor to the PICC
- 18) Secure the Flow Restrictor lightly to the patient's skin using appropriate adhesive tape e.g. Micropore
- 19) Insert the device into the dedicated pouch and site the pouch in the correct position

NB. Instruct the patient to keep the top of the Infusor as close to the level of the luer lock connector as possible.

- 20) Dispose of all used items.
- 21) Clean hands and remove apron.
- 22) Document procedure and condition of PICC exit site.

Appendix 5

Baxter OPAT Patient at Home booklet



Homecare Baxter
Patient Information

Appendix 6

Fridge monitoring log

Date	Current temperature	Maximum temperature	Minimum temperature	Thermometer reset Y/N	Recorded by	Actions taken if out of range

Appendix 7

Baxter LV10 Infusor Progression chart



Appendix 8

Competency assessment form for the principles of care and management of a Baxter LV10 Infusor

Competency Assessment form for principles of care and management of a Baxter LV10 Infusor

Practical assessment will be undertaken in the clinical area by another member of staff who is an experienced registered practitioner undertaking this skill on a regular basis. All criteria must be met to achieve competence.

Methods of Assessment include: Within both elements of this competency there must be at least a minimum of 2 examples of evidence from the list below.

1	Direct observation by Mentor The mentor directly observes the learner demonstrating a competency in the practice area and records the level of achievement.
2	Direct observation by an Expert Witness*/Work based Assessor Statement An Expert Witness or qualified work based assessor, who directly observes the learner demonstrating a competency in the practice area and records the level of achievement.
3	Interview Their mentor interviews the learner in order to assess understanding. The mentor/coach will record the level of achievement.
4	LEARN Evidence of successful completion of the online eLearning package. Evidence of successful completion of the knowledge assessment is acceptable
5	Simulation The learner could demonstrate their ability to perform clinical skills in a simulated situation, e.g. a skills laboratory if appropriate.

Formative assessments will be undertaken until the learner and mentor have agreed that a final summative assessment should be held.

Level	Description
1	Knows nothing about the skill.
2	Doubts knowledge and ability to perform the skill safely, without supervision.
3	Could perform the skill safely with supervision.
4	Confident of knowledge and ability to perform the skill safely.
5	Could teach knowledge and skills to others and can demonstrate initiative and adaptability to special problem situations.

Competency Assessment form for principles of care and management of a Baxter LV10 Infusor

I confirm that I am aware of my responsibilities, accountability and limitations in relation to practice relating to Central Venous Lines.

Candidate Name:		Date of Birth:	
Designation:		Ward/Department:	
Candidate Signature:		Date training completed:	
Competency Assessments completed			
Principles of care and management of Baxter LV10 Infusor		Date completed: (if applicable)	
Assessor Name: (PLEASE PRINT CLEARLY)			
Designation:			
Assessor Signature:			

Please return a *photocopy* of this page only to the:

NBT: Scan and e-mail to: StaffDevelopment@nbt.nhs.uk

UHBW: For entry onto your training record on the Trust Training Database MLE

Sirona: TBC

Please keep the complete original in your Portfolio

Competency Assessment form for principles of care and management of a Baxter LV10 Infusor

Remember

A competency level 4 (or above) must be demonstrated to provide assurance of knowledge and skills required to be perceived as being safe to continue without further education or assessment.

Re-assessment of this competency must be undertaken at 3 years.

This assessment must be kept in the staff member's personal file and a photocopy of the declaration page must be sent to the Staff Development Department for addition to the staff member's MLE training record.

Knowledge and Understanding Criteria

By the end of this assessment(insert name) should demonstrate knowledge and understanding and be able to apply the following:

Management of Patients with a Baxter LV10 Infusor					
The Practitioner will demonstrate a working knowledge of :	Method of assessment	Level of achievement	Comments from mentor / assessor	Confirmation of competency (please SIGN)	
				Mentor	Candidate
Clear knowledge and understanding of the Trust policies and guidelines in relation to Baxter LV10 infusor management.					
Competency in aseptic non-touch technique and can identify the key parts of ANTT relating to a Baxter LV10 infusor					

Demonstrate understanding of the key components of a Baxter LV10 Infusor, including how the infusor administers treatment.					
Demonstrate understanding of factors that can influence infusion time of a Baxter LV10 Infusor, including temperature, viscosity, access and device height.					
Knowledge of equipment required to administer a Baxter LV10 infusor, including connection and disconnection.					
Understand the process for safe delivery and transportation of a Baxter LV10 infusor.					
Knowledge of Baxter LV10 infusor stability and current approved treatment.					
Demonstrate understand of Baxter LV10 safety check before connection.					
Gain valid consent from the patient and demonstrates correct procedure for connecting a Baxter LV10 infusor					
Gain valid consent from the patient and demonstrates correct procedure for disconnecting or exchanging a Baxter LV10 infusor					
Demonstrate the safe disposal of LV10 Baxter infusor					
Demonstrated effective patient education and training to ensure safe patient care, including infusor pump progression					

Understands the additional safety measures relating to anaphylaxis					
The correct documentation for both Baxter LV10 infusor and PICC.					

Understands the additional safety measures relating to anaphylaxis					
The correct documentation for both Baxter LV10 infusor and PICC.					

Competency Assessment form for principles of care and management of a Baxter LV10 Infusor

Performance Criteria

By the end of the assessment **(insert name)** should demonstrate performance and be able to undertake the following:

The Practitioner will demonstrate knowledge of the following:	Method of assessment	Level of achievement	Comments from mentor / assessor	Confirmation of competency (please SIGN)	
				Mentor	Candidate
Equipment					
Patient					
Knowledge and Understanding					
Documentation					
Overall assessment of skill					

Appendix 9

Ancillary pack provided by Baxter

Pack 1 Items which must be included for first delivery
Refrigerator 1.8 cu/ft R5008W
Fridge Guideline
Fridge Thermometer
Sharp Bin 4L (PFS)
Sharp Bin 24L (intermates)
Plug Fridge Label
Fridge Magnet
Platform tray 14.5" x 16.25"

Pack 2 Items which must be included for first delivery
Alcohol & Chlorhexidine 2% wipes (Sanicloths CHG 2%) [box 100]
Alcohol Hand Gel 100 ml
Detergent Surface Wipes (Cliniwipes Kingsize) <200>
Gloves non sterile, non-latex, Small, medium, large <box 50>
Dressing Pack, to include sterile non-latex medium gloves, 2 x dressing towels, 5 swabs non-woven, Sterile apron – also includes disposal bag, 1 two compartment tray
Gloves, Sterile, non-latex, Small, Medium, large, x-large <box 50>
Chlorhexidine Pink 600 ml Hydrex Hand wash (PAED ONLY)
Swab Steret <100>
Vigon Bionnector
Codan Air Venting Needle – 1 per infusion
Syringes 10 ml Luer Lock [100]
Filter needles 18g [100]
Needle 21g – Green [100]
Extension Set 13.5 cm
Extension Set Codan 150 cm
20 g 5/8 16mm or 3/4 19mm Gripper Needle

Appendix 10

Frequently Asked Questions – for patient

How does my infusor work?

The infusor consists of an elastic reservoir (balloon) that moves the medicine along the tubing and through your PICC line. The small white connector is taped to your skin which controls how fast the medicine flows.

How should I position the Infusor while sleeping?

The infusor should remain at the same height as the PICC line; you should not place the Infusor on the floor or hang it above your head. Many patients find it comfortable to tuck the infusor as close to the PICC line as possible.

What should I do if the medication does not appear to be reducing over time?

Make sure that the infusion tubing or connections do not have any kinks or bends as these can cause an obstruction to the infusion rate. If you cannot identify any obvious issues, please contact Baxter.

How do I protect the Flow Controller and Filter whilst bathing/showering?

The infusor can get wet, but it is recommended that it should not be submerged in water. A suction cup shower hook is a great place to hang the Infusor while showering. You can bathe but you **must** keep your Infusor and Infusion Line away from any contact with the water.

Any concerns or questions, please contact the NHS@Home OPAT team, stating that you are a patient being cared for by them.