

1. Introduction and Who Guideline applies to

1.1 This Standard Operating Procedure describes the patient pathway and associated processes for patients with Acute Lymphoblastic Leukaemia (ALL) who are to be treated using an ambulatory service delivery model, as opposed to the customary inpatient model. This is to be used in conjunction with the Overarching Policy for Ambulatory Care pathways and the Standard Operating Policies referenced in the Policy.

1.2 Blinatumomab is a monoclonal antibody. It is a bispecific T cell engager antibody that enables the patient's own immune system to target and destroy cancer cells. Blinatumomab is an immunosuppressive agent.

Indication- Relapsed or Refractory Philadelphia chromosome-negative ALL.

Cycle- A single cycle is 28 days of a continuous infusion followed by a 14 day break.

2. Recommendations, Standards and Procedural Statements

2.1 Referral mechanisms

Suitable patients will be identified either through the Leukaemia MDT held each Monday afternoon or at the Transplant Planning meeting held on Tuesday afternoons. The relevant Leukaemia CNS has a role in informing other members of the team of patients selected as appropriate for ambulatory at the MDT and the transplant nurses have a similar role in communicating decisions from the Transplant Planning meeting if the Ambulatory Care CNS is not present.

2.2 Patient screening

2.2.1 Patient selection criteria:

- a) ECOG performance status 0-1
- b) 24 hour carer support including availability to drive patient to hospital in the event of an emergency (In the event of no carer being available but the patient is still considered suitable and wishes to follow the ambulatory model, a risk assessment will be undertaken and considered by the Multi Disciplinary Team)
- c) Patient must not be on IV antimicrobial therapy
- d) Patient must be fluent in written and spoken English
- e) Patient must be living within 30 minutes' drive of the hospital
- f) Satisfactory completion of the Patient education tutorial (see appendix 1)
- g) Ability to monitor own temperature and wellbeing
- h) Motivated to participate in the pathway

2.2.2 If the patient lives greater than 30 minutes from the hospital but it is agreed as appropriate by the consultant haematologist and MDT the patient can still use the ambulatory pathway- risk assessment is in place). An acute hospital (with an A&E and a Haematology department) within 30 minutes of the patient's home address will be identified and notified of the patient receiving Ambulatory treatment.

2.2.3 The following will be performed within 1 week prior to commencement of chemotherapy:

- FBC, U&E, Extended LFT, Bone, CRP, LDH (cycle 1 of chemotherapy) and any other tests deemed appropriate for specific regimens.
- Insertion of appropriate venous access or checking of current Hickman/PICC.
- Consent for Systemic Anti Cancer Treatment

2.3 Education

2.3.1 Patient and their carer must undertake an education programme delivered by an ambulatory care specialist nurse or senior nurse in Hambleton suite prior to the treatment regime commencing.

2.3.2 An agreement to confirm the patient and their carer understand their responsibility regarding risks and actions will be signed at the time of the education programme. See appendix 1.

2.4 Criteria for admission and Emergency Processes

2.4.1 Absolute criteria:

- a) Mucositis of sufficient severity to justify escalation of analgesia
- b) Hypotension unresponsive to fluid challenge
- c) Haemodynamic instability
- d) Marked tachycardia
- e) Hypoxia less than 93% on room air or raised respiratory rate
- f) Coagulopathy with associated bleeding
- g) Temperature $\leq 36.0^{\circ}\text{C}$ or $\geq 37.5^{\circ}\text{C}$ or rigors.
- h) Uncontrolled nausea and/or vomiting
- i) Patient failure to thrive
- j) Rising CRP

k) Clinicians request

2.4.2 Ambulatory patients in whom sepsis/infection is suspected or in whom a temperature of $\leq 36.0^{\circ}\text{C}$ or $\geq 37.5^{\circ}\text{C}$ is recorded must be reviewed by the Haematology team within 1 hour on Hambleton Suite or OAU.

2.4.3 Exceptions to this can be made if it is deemed clinically appropriate for the patient to remain at home. **This must be a triumvirate decision** agreed between the Consultant, Senior Nurse and the patient.

2.5 Timetable of Care

The following sequence of events will form the ambulatory service model:

Day and where to report	Interventions
Day 1: Attend Hambleton Suite	<ul style="list-style-type: none">• Assessment using UKONS assessment form and EWS• PICC line inserted (if not already in place)• Medical review and routine bloods• Weigh patient- ensure more than 45kg• 20mg IV dexamethasone pre medication (1 hour prior to first dose of each cycle)• Attachment of CADD pump- Blinatumomab 4 day infusion• Temperature am and pm• Regular medication as prescribed• Advised to take regular paracetamol for 48-72hrs as per protocol.• Supply spillage kit and cytotoxic waste bin to patient
Day 2-4: Home Rest Days	<ul style="list-style-type: none">• Temperature am and pm• Regular medication as prescribed
Day 5: Attend Hambleton Suite	<ul style="list-style-type: none">• Assessment using UKONS assessment form and EWS• Medical review and routine bloods• Change CADD pump bag- Blinatumomab 4 day infusion• Temperature am and pm

	<ul style="list-style-type: none"> • Regular medication as prescribed • PICC line care
Day 6-7: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed
Day 8: Attend Hambleton Suite	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Change of CADD pump- Blinatumomab 4 day infusion • Temperature am and pm • Regular medication as prescribed • PICC line care
Day 9-11: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed
Day 12: Attend Hambleton Suite	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Change CADD pump bag- Blinatumomab day infusion • Temperature am and pm • Regular medication as prescribed • PICC line care
Day 13-14: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed
Day 15:	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Change of CADD pump- Blinatumomab 4 day infusion • Temperature am and pm • Regular medication as prescribed • PICC line care
Day 16-18: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed

Day 19: Attend Hambleton Suite	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Change CADD pump bag- Blinatumomab day infusion • Temperature am and pm • Regular medication as prescribed • PICC line care
Day 20-21: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed
Day 22:	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Change of CADD pump- Blinatumomab 4 day infusion • Temperature am and pm • Regular medication as prescribed • PICC line care
Day 23-25: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed
Day 26: Attend Hambleton Suite	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Change CADD pump bag- Blinatumomab day infusion • Temperature am and pm • Regular medication as prescribed • PICC line care
Day 27-28: Home Rest Days	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed
Day 29: Attend Hambleton Suite	<ul style="list-style-type: none"> • Assessment using UKONS assessment form and EWS • Medical review and routine bloods • Remove CADD pump • Temperature am and pm

	<ul style="list-style-type: none"> • Regular medication as prescribed • PICC line care
Day 30-42:	<ul style="list-style-type: none"> • Temperature am and pm • Regular medication as prescribed • Continue care as an outpatient with attendance to Hambleton suite as per clinical need for monitoring of bloods, blood transfusions etc.

2.6 Routine Bloods

2.6.1 Unless clinically indicated otherwise patient should have the following blood tests taken:

- On each visit: Full blood count, Urea and Electrolytes, Bone, CRP
- Twice a week: Liver function Tests
- Twice a week if neutropenic: Galactomannan and Beta D glucan
- Any additional test which is requested by the medical team.

2.7 Blinatumomab Specifics

- Alert card to be carried by patient
- Blinatumomab lumen **should not be flushed**. Flushing causes an inadvertent bolus to be delivered to the patient. If in an emergency and directed by a Clinician, guidelines recommend withdrawing 10mls from the lumen before flushing through.
- Purple 'Blinatumomab infusing do not flush' sticker to be attached to giving set and lumen of PICC line that it is attached to.
- If a Blinatumomab infusion is stopped for 4 hours or more, a repeat dexamethasone dose may be required – clinical decision.
- Blinatumomab infusion must start on a Monday, Thursday or Friday within working hours.
- Patient must weigh more than 45kg

2.7 CADD Pump Specifics

- Successful drug delivery should be routinely checked at each patient visit
- If pump has problems at any time – the patient will be advised to telephone the Haematology Helpline. Ambulatory Care nurses or Hambleton Suite staff will be available to manage issues Mon-Fri 9-5. Out of these hours BMTU staff will be available to assist with queries.
- Contact Consultant on call if pump has to be stopped for any reason
- Patient has pump troubleshooting guide at home to deal with minor problems
- Each clinical area has a CADD folder which contains a CADD troubleshooting guide for clinical staff.
- Spillage kit and cytotoxic waste bin to be supplied to patient.

3. Education and Training

3.1 All nursing staff working in connection with patients being treated on an ambulatory care pathway will require assessment and training to care for these patients. This will also include use of the CADD Solis pump.

3.2 All chemotherapy trained staff on Ward 41, Ward 40, Ward 39, BMTU, Hambleton Suite, Osborne Day Care and Osborne Assessment Unit will be trained in the use of CADD pumps. Awareness education will also be given to non-chemotherapy trained staff on the wards and those who hold the haematology helpline phone so they have an understanding of the pump.

4. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead

5. Legal Liability Guideline Statement

The Trust will generally assume vicarious liability for the acts of its staff, including those on honorary contract. However, it is incumbent on staff to ensure that they:

- Have undergone any suitable training identified as necessary under the terms of this policy or otherwise.
- Have been fully authorised by their line manager and their CMG to undertake the activity.
- Fully comply with the terms of any relevant Trust policies and/or procedures at all times.
- Only depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible clinician it is fully appropriate and justifiable - such decision to be fully recorded in the patient's notes.

6. Key Words

Ambulatory Care

Pathway

Day Care

CADD Solis

Blinatumomab

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Anika Sirel, Natasha Woolgar	Executive Lead
Details of Changes made during review:	

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Appendix 1- Patient Education

University Hospitals of Leicester 
NHS Trust

Caring at its best

Name:
Date of Birth:
Hospital No:
NHS No:
Consultant:

Education programme for patient and carer involved in Ambulatory care pathway for Haematological conditions

In order for you to be accepted onto the Ambulatory care pathway you and your carer will need to attend an educational session. At the end of the educational session both you and your carer will need to confirm your attendance so a record can be made in your notes.

Topics to be discussed at the educational session:

1. Patient diary
2. Alert card for Haematology patients
3. Mouth care with an emphasis on Mucositis
4. Skin-tunnelled catheter care
5. How to take a temperature and record the results
6. Signs to watch out for:
 - Persistent nausea and vomiting
 - Poor fluid and food intake
 - Diarrhoea and constipation
 - Shivering
 - Shortness of breath
 - Swollen arm, ankles and legs
8. Problems associated with low platelets and haemoglobin
9. Taking medication and recording
10. What to do if you (the patient) are feeling unwell or need advice
11. Neutropenic diet
12. How to avoid infection
13. Personal care and managing the pump
14. Sex
15. Regime specific side effects - pyrexia (within 48 hours), cytokine release syndrome, infusion related reaction and neurological changes
16. Emergency Phone information

Please sign below to say you have attended this educational session and that you are willing to take part in the ambulatory care programme.

Patient's name:

Patient signature: Date:

Carer's name:

Carer's signature:Date:
Healthcare Professional's name:
Healthcare Professional's signature:Date:

Apply Patient Sticker

Name:

S number:

Date of Birth:

Blinatumomab Infusion Checklist

Please implement for all inpatients commencing or admitted on a
continuous Blinatumomab infusion. Check pump at least 4 hourly.

Time	Infusion Rate	Volume Remaining	Comments	Signature
00:00				
01:00				
02:00				
03:00				
04:00				
05:00				
06:00				
07:00				
08:00				
09:00				
10:00				
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