



NCCP NATIONAL HAEMATO-ONCOLOGY ADULT PATIENT PATHWAY: ACUTE LYMPHOBLASTIC LEUKAEMIA (ALL) / ACUTE LYMPHOBLASTIC LYMPHOMA (LBL)

Version	Date	Amendment	Approved By
1	28/07/2023		NCCP Haemato-oncology Clinical Leads Group
2	11/12/2023	Addition of text regarding: <ul style="list-style-type: none">- Scope and AYA pathways in Section 2- Immunophenotyping and tumour conferences in Section 3- AYA pathways in Section 5- Follow-up in Section 7	NCCP Haemato-oncology Clinical Leads Group

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

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1 Background

Acute lymphoblastic leukaemia (ALL) is an uncommon acute haematological malignancy, representing approximately 11% of all leukaemias in Ireland (1). Over 60 people are diagnosed with ALL in Ireland every year, most commonly adolescents and young people between the ages of 15 and 25 (1, 2).

Acute lymphoblastic lymphoma (LBL) is a rare form of high-grade non-Hodgkin lymphoma that develops from immature lymphocytes. It can develop from B cells or T cells and typically affects younger people. It is very similar to ALL and is treated in the same way (3).

The prognosis for adult patients with ALL / LBL is less favourable than for children and adolescents (4). Treatment of ALL / LBL is based on optimisation of chemotherapy, stem cell transplantation, supportive care and more recently, complemented by targeted therapy (5).

Acute haematological malignancies such as ALL / LBL require complex treatment and are resource intensive (6). In line with Recommendation 24¹ of the National Cancer Strategy 2017-2026, such treatment should be delivered in a limited number of centres with appropriate facilities in place (6).

The Strategy has categorised haematological malignancies into the following three outcome-focused groups and recommended that they should be considered separately when organising services, as patients will require different facilities depending on the type and aggressiveness of their cancer and the expected outcome:

Outcome-focused Group 1: Haematological malignancies treated with curative intent requiring complex inpatient care

Outcome-focused Group 2: Hodgkin lymphoma and other aggressive non-Hodgkin lymphomas

Outcome-focused Group 3: Lower grade chronic haematological malignancies

¹ National Cancer Strategy 2017-2026; Recommendation 24: The NCCP will develop appropriate MDT, centralisation and treatment arrangements to meet the diverse needs of patients with haematological cancers.

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In line with the above recommendation, this pathway will focus specifically on ALL / LBL (belonging to Group 1) with the purpose of defining referral, tumour conference and treatment pathways for new and relapsed adult patients² diagnosed with ALL / LBL.

2 Scope and Methodology

This document is built around the recommendations of the National Cancer Strategy 2017-2026 (6), the NCCP Oncology Medication Safety Review Report (7), the NCCP Systemic Anti-Cancer Therapy³ (SACT) Model of Care (2022) (8) and Slaintecare (9).

The following are not within the scope of the document:

- Patient pathways for children (0-16 years)
- Patient pathways for adolescents and young adults (AYA) (16-25 years) where there is an agreed national pathway under the AYA programme. Strategies for the provision of SACT services for children and adolescents and young adults with cancer are being managed in a separate work stream within the NCCP.
- Details of clinical trials
- Specific laboratory guidelines for diagnosis of haematological malignancies

It is important to note that this document has been developed as a pathway and not a clinical guideline. As such, it does not provide treatment guidelines or recommendations.

The document has been informed by published literature as well as local and international practice. The pathway is not designed to be exhaustive, but should act as a guide.

² Strategies for the provision of SACT services for children and adolescents and young adults with cancer are being managed in a separate work stream within the NCCP.

³ SACT (systemic anti-cancer therapy) involves systemic treatment for cancer; involving parenteral and oral anti-cancer therapies, including but not limited to chemotherapy, targeted therapies and immunotherapies.

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3 Referral pathways

The ALL / LBL Patient Pathway is illustrated in Appendix 1.

1. Patients with acute leukaemia should be referred immediately to a haematologist for assessment (10). Referral policies should be available to promote prompt and appropriate referral (11).
2. An efficient triage, transfer and workup process is critical when results from a blood test or bone marrow assessment / tissue biopsy indicate that a patient may have acute leukaemia (12).
 - a. Immunophenotyping of samples needs to consider the future management of minimal residual disease (MRD) monitoring.
3. These patients should be urgently referred to a haemato-oncology inpatient unit which treats ALL / LBL or Emergency department⁴.
4. All new and relapsed patients should be referred to the tumour conference for confirmation of diagnosis, prognosis and management plan, taking into account their performance status, needs and co-morbidities.
5. Planning for an allogeneic stem cell transplant should begin at the time of diagnosis in conjunction with the transplant centre. A joint approach with elderly care physicians and palliative care teams may be appropriate in patients with poor prognosis disease and who are not eligible for transplant.

3.1 Tumour conferences

A standard SOP guidance for haemato-oncology tumour conferences⁵ has been developed by the NCCP. This document may be adopted and adapted as appropriate to local processes.

⁴ NCCP SACT Model of Care, Recommendation 24: Type 3 SACT hospitals and non-SACT hospitals with an emergency department should have processes in place for the assessment, rapid referral and transfer of patients to an acute SACT hospital in a timely manner.

⁵ NCCP Haemato-oncology Tumour Conference - Standard Operating Procedure Guidance. Available at: <https://www.hse.ie/eng/services/list/5/cancer/profinfo/tumour-conference-sops/haemonc-tumour-conference.pdf>

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1. Tumour conferences should take place for:
 - a. all new patients with ALL / LBL in order to confirm the diagnosis and treatment plan
 - b. all patients with a restaging assessment of response to treatment
 - c. all patients for whom an allogeneic stem cell transplant is a consideration
 - d. all patients where a new line of therapy needs to be considered

2. Information to be captured and documented prior to or during the tumour conference may include:
 - a. demographic information
 - b. referring physician and / or GP
 - c. performance status
 - d. an indicator of co-morbidities (e.g. co-morbidity score)
 - e. any relevant history
 - f. details of fertility preservation if available
 - g. pertinent positive and negative findings on physical examination (splenomegaly, rashes, etc)
 - h. full blood count (FBC), haematinics, liver function tests (LFTs), urea and electrolytes (U&E), lactate dehydrogenase (LDH), urate, serum protein electrophoresis (SPEP), peripheral blasts
 - i. virology screen
 - j. human leukocyte antigen (HLA) screen of patients and siblings in stem cell therapy (SCT) eligible patients
 - k. bone marrow aspirate and trephine histology
 - l. bone marrow aspirate immunophenotyping
 - m. molecular, cytogenetic, Ph/MLL/Ph like gene rearrangements immunoglobulin heavy chain (IgH) / T cell receptor (TCR) (critical for MRD assessment) at diagnosis and at relapse

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- n. specific diagnostic ALL / LBL sub-type
- o. relevant imaging (e.g. CT staging)
- p. echocardiogram (ECHO) study
- q. risk score
- r. availability of a clinical trial / research study and if the patient is eligible
- s. patient views and preferences, if known
- t. the question being posed for the tumour conference
- u. management and treatment plan
- v. clinical nurse specialist / designated contact person
- w. named consultant

3.1.1 Tumour conference considerations

1. Patients with ALL / LBL should be discussed at a tumour conference within two weeks of diagnosis – it is expected that treatment would have commenced prior to the tumour conference.
2. Where there is a need for urgent treatment, new patients should be commenced on an appropriate therapy and scheduled for discussion at the next tumour conference.
3. The GP should be informed of the tumour conference outcome in line with NCCP guidance.
4. Location of tumour conferences:

In line with the National Cancer Strategy 2017-2026, the NCCP are developing appropriate MDT, centralisation and treatment arrangements to meet the diverse needs of patients with haematological cancers. Once these arrangements are approved, patients should be discussed at the appropriate tumour conference within these approved arrangements.

5. All ALL / LBL patients should have their care discussed in a complete⁶ tumour conference attended by members involved in the diagnosis, treatment, or care of a particular patient,

⁶ A complete tumour conference is defined as a tumour conference that follows (as appropriate) the NCCP standard operating procedure for haemato-oncology tumour conferences and provides a recommendation on the patient's treatment plan.

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and all the clinicians in the tumour conference should regularly treat patients with ALL / LBL.

6. For a resilient service, there should be adequate resources and supports in place for tumour conferences. Please refer to the NCCP Haemato-oncology Tumour Conference SOP Guidance⁵ for details of requirements.
7. Required attendees at the tumour conference should include:
 - a. Two Consultant Haematologists
 - b. Clinical nurse specialist (CNS) / other nurses
 - c. Consultant Histopathologist / Haematopathologist where indicated
 - d. Consultant Medical Oncologist, where indicated
 - e. Non-consultant hospital doctors (NCHDs) in Haematology / Medical Oncology with cancer service rotations
 - f. Tumour conference coordinator
 - g. Data manager
 - h. Administrative support
 - i. Consultant Radiologist, where indicated.
 - j. Consultant Radiation Oncologist, where indicated
8. Desirable attendees may include other relevant disciplines, as appropriate, depending on the nature of the cases to be discussed.
9. Individual clinicians should be responsible for discussing the tumour conference recommendations with their patients, who should have the opportunity to be informed of the outcome of the tumour conference (13).

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4 Patient information / support

Patient information / support should be provided in line with the recommendations of the NCCP Oncology Medication Safety Review Report⁷ and the NCCP SACT Model of Care⁸ (7, 8).

5 Treatment

1. Aggressive haematological malignancies such as ALL / LBL are potentially curable with intensive chemotherapy⁹ (11).
2. Treatment for ALL / LBL follows strict protocols. Patients are considered for clinical trials if available / appropriate (Refer to Section 8: Research / Clinical Trials).
3. Treatment regimens for individual patients e.g. UKALL, will be decided as per tumour conference.
4. There is a NCCP SACT Clinical Advisory Group for ALL in place. Their role includes overseeing the development and review of national chemotherapy regimens and developing, reviewing and approving clinical guidelines for new drugs and new indications for existing drugs that are in the reimbursement process.
5. In line with the National Cancer Strategy 2017-2026 (6), patients diagnosed with acute haematological malignancies such as ALL / LBL who are treated with intensive chemotherapy should be cared for in a designated number of centres capable of accepting patients on transfer within 24 hours of diagnosis. The NCCP SACT Model of Care (2022) states that patients diagnosed with ALL / LBL and treated with intensive chemotherapy should be cared for in a Type 1 SACT hospital¹⁰ (8).

⁷ NCCP Oncology Medication Safety Review Report; Recommendations 29-32, 36, 37

⁸ NCCP SACT Model of Care; Recommendations 1 and 2

⁹ Intensive chemotherapy is defined as that which is anticipated to result in severe neutropenia of 0.5×10^9 /L or lower for greater than 7 days, in addition to other potential organ toxicities, co-morbidities and frailty.

¹⁰ NCCP SACT Model of Care, Recommendation 7: Certain specialist, low volume, often in-patient, complex SACT regimens should be centralised in a limited number of Type 1 or Type 2 SACT hospitals - this includes specialist haemato-oncology services.

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6. Where circumstances allow, less intensive treatments and supportive care can be provided closer to the patient's home in cooperation with the treatment centre.

5.1 Summary of main considerations in the treatment of ALL / LBL

1. Appropriate specimens should always be taken before therapy is started.
2. ALL / LBL is a curable disease in young patients that becomes harder to treat as the patient ages. Fewer patients are cured as age advances and therapeutic complications become increasingly common (14).
 - a. All patients should be treated with age-appropriate therapy.
 - b. For AYA patients, there should be engagement with the relevant AYA centre once the pathways are established. AYA patients can be discussed at the relevant local tumour conference but they must also be referred to the National AYA MDM once the pathways are established.
3. As the disease is rare and treatment is complicated, there are many areas where best practice is not defined.
4. Acute haematological malignancies such as ALL / LBL require comprehensive multidisciplinary team (MDT) availability at all times, single high efficiency particulate air-filtered (HEPA) rooms, day unit and ideally admission facilities that are separate from the general hospital emergency department and access to other key services, especially intensive care, radiology and laboratory medicine (including transfusion medicine) on both an emergency and elective basis (6).
 - The hospital should also participate in clinical trials for patients with ALL / LBL where available.
5. Experienced specific supportive care and expertise is required.
 - a. ALL and LBL pertain to the Strategy's outcome-focused Group 1 i.e. haematological malignancies treated with curative intent requiring complex inpatient care. They require comprehensive multidisciplinary team (MDT) availability at all times (6).

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- b. The European Working Group on adult ALL recommends that patients (being treated for curative intent) should be treated in centres which see at least five new patients a year (including AYA patients) (5).

Note: Centres caring for patients who are receiving high-intensity chemotherapy should provide high-intensity (non-transplant) chemotherapy for induction or re-induction of remission to a minimum of 10 patients per year who have new or relapsed haematological malignancies and who are at risk of more than 7 days of neutropenia of 0.5×10^9 /litre or lower (11).

6. Adherence to the detail and timing of scheduled treatment strategies is important. Minimising therapeutic delays has a positive impact on outcomes.
7. Recognising complications of therapy quickly and being aware of which complications require treatment cessation and which do not are also vital.
8. Allogeneic bone marrow transplant is currently a common element of patient management for patients aged 25 years and over. Patients identified as transplant eligible at presentation should be referred for consideration of allogeneic transplantation at the earliest opportunity.

6 End of treatment information

The tumour conference outcome form and clinic letters will serve to communicate new lines of treatment to the GP (14). End of treatment is defined as the end of primary remission induction therapy and / or when there are any significant changes in treatment (14).

6.1 Treatment summary and care plan

There are two related but distinct documents which patients should be given at the end of treatment.

6.1.1 Treatment summary

A treatment summary provides a summary of the cancer treatments received by the end of the first treatment and planned follow-ups. The aim is to provide information not only to the patient, but also to the GP about possible consequences of cancer and its treatment, signs of recurrence

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and other important information. The National Cancer Strategy 2017-2026 recommends that all hospitals should offer patients a patient treatment summary and care plan as part of their support (6).

6.1.2 Care plan

A care plan can be generated as a result of a holistic needs assessment and would be the agreed plan between the patient and healthcare professional about how the identified areas of concern will be addressed. This may cover provision of information, onward referral for specialist assessment and intervention, or patient-related matters such as engagement with employer / human resources department regarding graduated return to work options.

6.2 End-of-treatment consultation

An end-of-treatment consultation should be offered to every patient. This should include an end-of treatment holistic needs assessment and associated written care plan, and should also include the discussion and provision of a comprehensive treatment summary.

The NCCP SACT Model of Care states that on completion of SACT, relevant information must be given to each patient, the patient's GP and any other primary care facility that the patient is linked with (8).

7 Follow-up arrangements

Patients on treatment will need inpatient admission, usually during phase 1 induction, and often for some part of phase 2 and intensification. When discharged, frequent monitoring is required and is dependent on the therapeutic phase of treatment and the degree of supportive care required (15-17).

The NCCP SACT Model of Care (2022) recommends that an individual follow-up care plan should be provided to each patient (8).

Patients may have shared follow-up care between a specialist site and the local treating hospital. These arrangements must be clearly outlined so that the patient knows where to attend in an

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emergency and understands the pathways of communication between the sites. These arrangements must be documented in PPPGs (**Refer to local policy**).

Patients who have completed chemotherapy will be followed up according to Table 1 below, which can be modified according to the patient’s individual risk.

Table 1: Follow-up of patients with ALL / LBL post chemotherapy

Year 1 & 2	3 monthly
Year 3 & 4	4 monthly
Year 5	6 monthly
Year 6 onwards	Annually in long term follow-up / survivorship clinics or discharge to GP

The National Cancer Strategy 2017-2026 recommends that primary care services should be supported by hospital-based care with specialist oncology nurse-led clinics, using remote follow-up where appropriate (6). For nurse-led SACT services, dedicated pathways for access to haemato-oncology specialist teams must be in place (8).

8 Research / clinical trials

All patients should be considered for a clinical trial wherever possible (14). This is in line with the National Cancer Strategy 2017-2026 (6) and the NCCP SACT Model of Care (2022), both of which recommend that patients should have access to a clinical trial where clinically appropriate (8). The National Cancer Information System (NCIS) will support the gathering of cancer clinical trial activity.

For patients with long distances to travel to the trial centre, the option of shared care may be considered (14):

- If the local hospital has HSE Research Ethics Committee¹¹ approval, care may be transferred to the local unit for the maintenance phase of care.

¹¹ <https://www.hse.ie/eng/services/list/5/publichealth/publichealthdepts/research/rec.html>

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- If the local hospital does not have the trial open, then bloods may be taken and analysed locally, but all clinical decisions must be taken by the trial centre.
- For those centres wishing to participate in shared care, clear documentation of shared care arrangements must be undertaken with communication to centres, the GP and the patient.

9 Data requirements

Accurate data collection is essential to monitor outcomes, and the collection of this information, particularly clinical data, remains the responsibility of the members of the tumour conference with support from a data manager. NCCP standardised haematology tumour specific datasets should be used where available.

As per Recommendation 14 of the NCCP SACT Model of Care (2022), all SACT services should have a data and information management strategy document (8). The implementation of NCIS will support many aspects of data and information management in hospitals. Where possible, a shared patient record should be in place to facilitate the sharing of patient records between hospitals and primary care (8). Data managers, tumour conference co-ordinators and other staff should be in place at designated cancer centres to facilitate this (6).

The National Cancer Registry Ireland (NCRI) collects, collates and analyses data on cancer incidence, staging, treatment and survival. Mortality data is collected and published by the Central Statistics Office (6).

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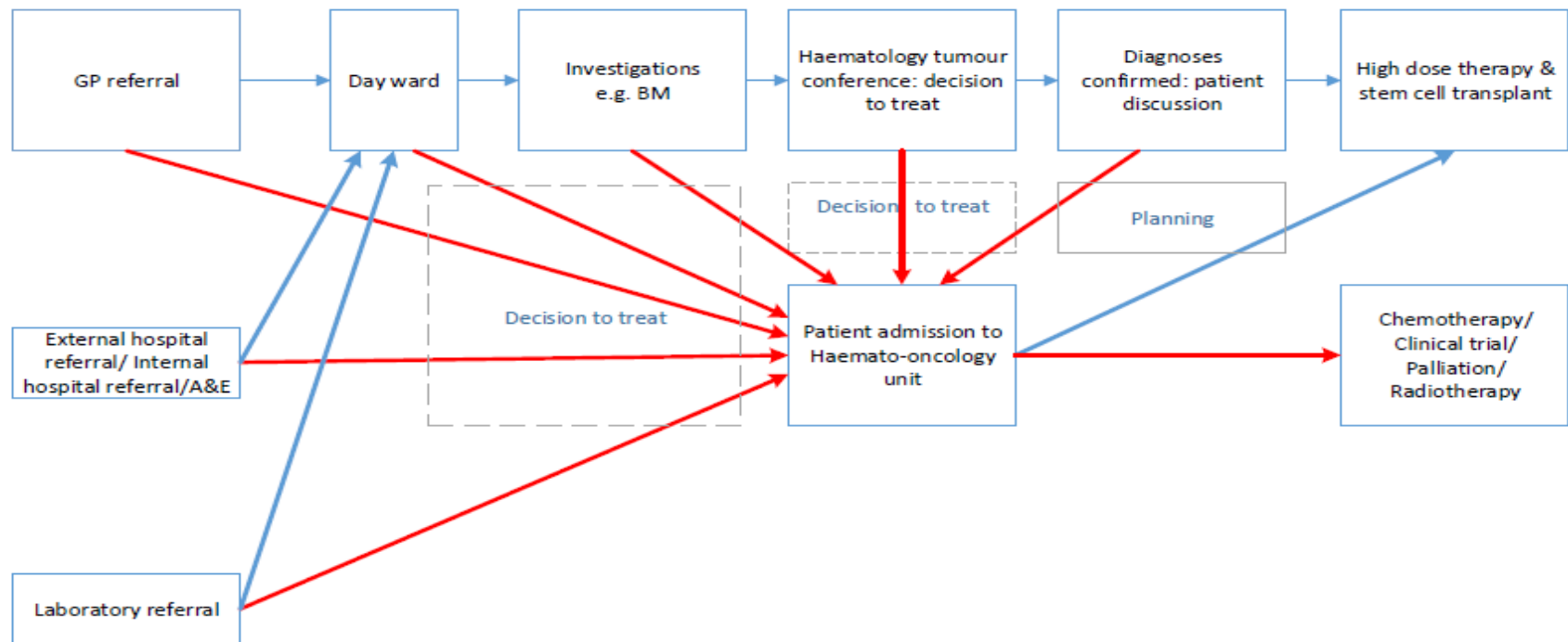
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Appendix 1. Acute Lymphoblastic Leukaemia / Acute Lymphoblastic Lymphoma Patient Pathway

Treatment of acute leukaemia is usually urgent and occasionally presents as a medical emergency. Therefore, treatment discussions and decisions are generally made before the tumour conference takes place. However, the treatment decision and long-term management is discussed and approved at the next tumour conference (urgent case pathway depicted in red arrows).



Legend:
 GP = General Practitioner
 A&E = Accident & Emergency