Advanced Therapy Treatment Centres

Midlands-Wales Advanced Therapy Treatment Centre

Example Adult CAR T Cell Shared Care Guidelines

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Background

Chimeric antigen receptor (CAR) T cells are innovative therapies licensed to treat relapsed/refractory haematological malignancies. As they are highly complex, Advanced Therapy Medicinal Products (ATMPs), treatment is undertaken at specific UK centres, with referrals from large geographical areas, which may lie outside of existing secondary-tertiary referral networks.

Due to the potential for serious adverse effects and the requirement for long term supportive care and follow up, it is vital to establish robust shared care arrangements. This exemplar guideline suggests roles and responsibilities between CAR T cell referring centres and treatment centres. It also outlines common late adverse effects that may occur when patients have returned to their referring centre. The shared care structure and description of late adverse effects is specific to adult patients receiving CAR T cell therapy for currently approved leukaemia and lymphoma indications. The guideline will require adaptation to reflect local processes and new indications.

The diagnosis and management of acute CAR T cell toxicities are not considered in this document, but national guidance is available from the Pan UK Pharmacy Working Group for ATMPs;

https://www.sps.nhs.uk/wp-content/uploads/2020/12/Diagnosis-and-medical-management-of-acute-CAR-T-cell-toxicities-in-Adults-V1.pdf

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1. General principles of shared care for CAR T cell patients

Effective shared care between the CAR T Cell treatment centre and the referring centre is essential before, during and after therapy. This requires:

- Good communication between the treatment centre and referring centre, with designated individuals for each centre.
- Treatment centres are contracted to provide 30 days of post treatment care (NHS England commissioned CAR T Cell centres, may differ in devolved nations)
- Intensity of post CAR-T care is patient dependent and flexibility may be required
- Treatment centre should be contacted to discuss management of any complications after the patient returns to the referring centre
- The treatment centre will formally 'hand-over' patients at day 30 to referring centre.

2. Authorised personnel/training required

All healthcare professionals involved in the shared care of patients pre and post CAR-T cell therapy.

3. Procedure

3.1. Pre CAR T Cell admission

Preliminary discussion

- Preliminary discussion of potential patients with the treatment centre, with advice given by the treatment centre, where required, on eligibility criteria

Referral to treatment centre

- Patients meeting criteria for CAR T cell therapy should be formally referred to the treatment centre as soon as possible
- An example referral form for lymphoma CAR T cell patients is included in Appendix 1
- Lymphoma patients meeting treatment criteria will be reviewed by the Lymphoma National CAR T Cell Clinical Panel for approval
- Acute lymphoblastic leukaemia (ALL) patients do not require national panel approval, although clinicians may discuss complex cases with colleagues nationally

CAR T Cell manufacture timescales

Due to a complex manufacturing process and limited capacity, manufacture of CAR T cells can be expected to take 4 weeks from the date of leukapheresis. The treatment centre should inform the referring centre of expected timescales and of any manufacturing delays.

Investigations

The following investigations and procedures will be performed by either the referring centre or the transplant centre, depending on the individual patient circumstances. The responsibility for pre-CAR T cell investigations for individual patients should be determined at the point of referral.

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Table 1. Summary of investigations required pre CAR T cell therapy

Investigation Type	Investigation Type
Microbiological/ Virology markers	Human T-cell Lymphotropic Virus 1+2 antibody, Toxoplasma IgG Treponemal serology HIV 1+2 antigen/antibody & HIV-1 RNA Hepatitis B surface antigen, core antibody & PCR Hepatitis C serology & RNA Hepatitis E RNA CMV serology & PCR EBV serology & PCR Varicella zoster immunoglobulin MRSA screening
Documentation of disease status	**Lymphoma;** PET scan and lymph node biopsy* **ALL;** Bone marrow biopsy and immunophenotyping Lumbar puncture & CNS MRI if history of CNS disease or neurological symptoms of concern
Pulmonary function tests	Spirometry, lung volumes, transfer factor, 6 minute walking test
Other assessments of fitness to proceed/risk of toxicity	Chest X-ray Echocardiogram and ECG Assessment of hepatic & renal function FBC, U&Es, LFTs, CRP, TFTs, B_{12} & folate, ferritin, Ca2+, Mg2+, PO4-, LDH HPLC sickle and thalassaemia (if at risk population) ABO and Rhesus status Direct Coombs test. Clotting screen Baseline immunoglobulin levels and paraprotein Pregnancy test ECOG Performance Status

*Biopsy details required include cell of origin and double hit/double expresser status. If lymph node biopsy cannot safely be undertaken, discuss with treatment centre.

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Communication with other departments/specialities

Transfusion service to be alerted to the need for irradiated blood products

Bridging/Holding Therapy

- **Holding therapy** refers to the use of any systemic anti-cancer therapy or radiotherapy to control disease between patient registration/approval and leukapheresis.
- **Bridging therapy** refers to the use of any systemic anti-cancer therapy or radiotherapy to control disease between leukapheresis and lymphodepletion/CAR T cell administration.
- The aim of bridging or holding therapy is to control disease progression whilst minimising toxicity, as opposed to obtaining a remission pre CAR T cell therapy.
- The choice of therapy should be discussed at the earliest opportunity with the treatment centre.
- National guidance on medication restrictions for CAR T Cell patients (**https://www.sps.nhs.uk/articles/medication-restrictions-for-patients-having-car-t-cell-therapy/**), should be followed wherever possible, as the observation of adequate wash out periods for prior therapy will optimise the chances of success of CAR T cell therapy.
- The treatment centre should be informed as soon as possible of any delays in starting holding or bridging therapy as this is likely to impact on the timing of leukapheresis or CAR T cell administration respectively.

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3.2 Admission to Treatment Centre for lymphodepletion and CAR T cell administration

Day 6 to day 0 (Treatment centre)

- Patients admitted to start lymphodepleting chemotherapy (this may also be undertaken on an ambulatory basis)
- CAR T cells will be administered on day 0

Day 0-14 (Treatment centre)

- CAR T cell recipients will remain inpatients for a minimum of 14 days post cell infusion (note this may vary locally, manufacturers stipulate a minimum of 10 days)
- Patients will only be discharged once any cytokine release syndrome (CRS) has resolved and they have an Immune Effector Cell Encephalopathy (ICE) score of 10/10

Day 14-30 (Treatment centre)

- **CAR T cell recipients must have a carer available 24 hours a day in order to be discharged from inpatient facilities. Where this is not feasible, the patient will remain an inpatient until day +30.**
- **Accommodation;** CAR T cell recipients will reside in near-hospital accommodation (to the treatment centre) if their home address is more than a 2hr drive from the treatment centre as advised by CAR T cell manufacturers. In practice, some treatment centres employ a more cautious approach of a limit of a 30 minute drive from the treatment centre.
- **A discharge summary** documenting inpatient course and medication on discharge to the outpatient setting should be forwarded to the patient's GP and referring centre. All out-patient clinic letters should also be forwarded to the patient's GP and referring centre.

  Patient review; CAR-T recipients will be reviewed daily in person or by videolink/telephone from discharge until day +30. As a minimum, patients will have a face to face assessment twice weekly, up to D+30 for clinical review including:

  - ICE score
  - Physical examination
  - Review of medication
  - FBC, U+Es, LFTs, CRP, ferritin, clotting screen, Ca2+, Mg2+, PO4- and LDH.
- **Disease re-assessment;** The treatment centre will arrange the following. Re-assessment may vary according to local guidelines and the patient's clinical status
  - Lymphoma: Day 30 PET/CT
  - ALL: Day 30 Bone marrow aspirate and trephine +/- imaging

3.3. Day 31-100: Shared care between referring and treatment centres

General Considerations:

- CAR-T recipients will carry a CAR-T Cell Alert Card and will receive the patient education and package leaflet for the relevant CAR T Cell product. The use of patient wristbands to alert healthcare providers to prior CAR T cell therapy is also being considered.
- Patients are to refrain from driving, using machines or activities that require alertness for 8 weeks post CAR-T therapy or beyond 8 weeks until resolution of neurological symptoms where applicable.
- All healthcare professionals to ensure that they and the patient (and their carer) are alert to the possibility of altered consciousness for 8 weeks following CAR T cell therapy.
- Patients must not donate blood, organs, cells or tissues lifelong, following treatment with CAR T cell therapy.
- Prior therapy with tisagenlecleucel may result in a false-positive result for some commercial tests for HIV nucleic acid (NAT).

Referring centre responsible for;

- Prescribing and administering routine treatment/support e.g. blood products, anti-infective supportive care
- Being alert to possibility of altered consciousness for 8 weeks following CAR T cells
- Informing treatment centre if any signs or symptoms of ICANs or disease progression
- Arranging disease re-assessment;
  - Lymphoma; Day 90 PET-CT
  - ALL; Monthly bone marrow biopsy for 6 months

Treatment centre responsible for;

- Minimum fortnightly follow-up at Treatment Centre, with review of FBC U+Es, LFTs, BMT viral PCR screening for EBV, CMV and adenovirus (if previous allograft, EBV+ or late derangement of LFTs)
- Be alert to possibility of altered consciousness for 8 weeks
- Monthly monitoring of IgG levels
- Providing advice to referral centre on management on possible ICANs and arranging transfer of patient to treatment centre where appropriate

3.4. Day 100 onwards (Referring centre)

Referring centre responsible for;

- Minimum monthly clinical review at referring centre to 6 months (may be more frequent if ongoing problems)
- Arranging on-going disease reassessment
  - ALL; Monthly bone marrow biopsy for first 6 months, then every 2 months until 12 months post CAR T cells, then every 3 months until 2 yrs post CAR T cells
  - Lymphoma; PET CT Scan at 6 and 12 months. An additional scan is also indicated at 9 months if a complete metabolic remission is not achieved at 6 months

Treatment centre responsible for;

- Long term follow up as detailed in section 3.5 in addition to monthly review by the referral centre.

3.5. Long term follow up at treatment centre

- Treatment centre review at landmarks of 3, 6, 9, and 12 months as a minimum and then annually thereafter.
- Follow-up will continue at the treatment centre for 15 years, as part of post-authorisation safety surveillance, with reporting of patient safety and efficacy data in accordance with EBMT registry requirements. Any adverse effects should also be reported as for other medicines via the Medicines Healthcare Regulatory Agency (MHRA) Yellow Card Scheme and to the manufacturer.
- Patients will be referred to the Late Effects Clinic by the treatment centre at around 5 years post CAR-T cell therapy.

4. Supportive care

This section outlines supportive care expected to be required in the period from Day +30 onwards only and does not consider the acute in-patient period post CAR T cell administration and management of cytokine release syndrome (CRS), immune effector cell associated neurotoxicity (ICANs) or haemophagocytic lymphohistiocytosis (HLH). Details of acute toxicity management is available from the Pan Pharmacy Working Group for ATMPs **https://www.sps.nhs.uk/wp-content/uploads/2020/12/Diagnosis-and-medical-management-of-acute-CAR-T-cell-toxicities-in-Adults-V1.pdf**

Table 2. Summary of anti-infective supportive care[1]

Prophylaxis type	Drug	Dose	Duration/notes
Herpes simplex virus	Aciclovir	400mg PO BD	For 12 months or until CD4+ ≥0.2 x10^9/L
Pneumocystis jiroveci pneumonia (standard)	Co-trimoxazole	480mg PO OD or 960mg three times a week	From lymphodepletion for 1yr or when CD4+ ≥0.2 x10^9/L. May be started later according to local protocols
Pneumocystis jiroveci pneumonia (alternative)	Pentamidine	300mg monthly nebulised	Other alternatives include atovaquone, dapsone
Antifungal	Not routinely recommended, but consider if prolonged neutropenia, prior corticosteroids, prior allogeneic haematopoietic stem cell transplant or prior invasive aspergillosis		
Antibacterial	Not recommended, but may be considered for prolonged neutropenia in accordance with local guidelines. Note that ciprofloxacin has the potential to reduce seizure threshold.		
Influenza vaccination			From 1 month after CAR T cell infusion, also administer to adult household contacts
Re-vaccination for recipients of previous allogeneic HSCT			Proceed on resolution of B-cell aplasia
Covid-19 Vaccination			As per UK national guidance and BSBMTCT/ EBMT recommendations*

***Consult the BSBMTCT & EBMT website for their most recent COVID-19 vaccination guidance**
https://bsbmtct.org/ https://www.ebmt.org/covid-19-and-bmt

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Table 3. Summary of other supportive care

Prophylaxis/ treatment type	Drug	Dose	Duration/notes
Anti-epileptic	Levetiracetam	750mg PO BD	Prophylaxis for patients at increased risk of neurotoxicity only. Started at first sign of ICANs in all other patients. **To be stopped by or on the advice of the treatment centre.** Review 30 days after the last episode of ICANs or CAR T cell administration, whichever is later
Treatment of neutropenia	Granulocyte colony stimulating factor (GCSF)	As per product SPC	Avoid in acute period post CAR T cell therapy (may worsen CRS). May be used from day +14 onwards, providing any CRS/ICANs resolved[1]
Low IgG	Immunoglobulin	As per product SPC	For patients meeting **national criteria[2]***, following approval by Sub-Regional Immunoglobulin Panel
Corticosteroids	**AVOID** unless for the treatment of CRS or ICANs (seek advice from treatment centre), or life threatening reaction		

***These criteria apply to England only and processes may differ in devolved nations**

5. Late Effects

All adverse effects should be reported via the Medicines and Healthcare Products Regulatory Agency (MHRA) yellow card scheme, via relevant registry and to the manufacturer. Adverse effects should also be communicated between referral and treatment centre.

Prolonged Cytopenias

Cytopenias are a common adverse effect and may depend upon prior therapy as well as CAR T cell administration. Prolonged cytopenias are defined as occurring beyond day +28-30 and are estimated to occur at the following frequency respectively for each product (Table 4).

Approximately one-third of patients have prolonged neutropenia (beyond day +30) and up to 20% of patients have neutropenia lasting more than 90 days[1].

Table 4: Incidence of prolonged Grade 3 or higher cytopenia by product type[3-5]

Prolonged cytopenia (G3 or higher)	Yescarta	Tecartus	Kymriah B-ALL paeds/TYA	Kymriah DLBCL
Neutropenia	26%	37%	54%	25%
Thrombocytopenia	24%	38%	42%	39%
Anaemia	10%	17%	13%	14%

Prolonged cytopenia can be managed by administration of granulocyte colony stimulating factor (GCSF) from day +14 onwards where indicated. Any episodes of CRS or ICANS must have resolved before GCSF is administered due to the potential for exacerbation with GCSF[1].

Infection

Infection is a common adverse effect following CAR T cell therapy, occurring mainly within 30 days. Beyond 30 days, infections are predominantly viral, often as a result of lymphopenia and include respiratory viral infections and cytomegalovirus!.

Although fungal infections are uncommon post CAR T cell therapy, risk factors include previous allogeneic stem cell transplant, prolonged periods of neutropenia (neutrophils < 0.5 x 10^9/L) both pre and post CAR T cell therapy and prolonged use of corticosteroids as bridging therapy.

Recurrent sino-pulmonary infections may be associated with B cell aplasia. Refer to B cell aplasia section for management.

Secondary Malignancies

As for all patients previously treated with chemotherapy +/- radiotherapy, CAR T cell patients are at risk of secondary malignancy. There is also a rare risk of secondary malignancy associated with administration of genetically modified cells, due to the possibility of insertional mutagenesis. As a result, all patients with secondary malignancy must be reported to the respective CAR T cell manufacturer, in addition to registry and MHRA reporting requirements and investigated accordingly to establish any potential link with CAR T cell therapy. This may include sampling of peripheral blood to monitor for replication competent vector and core tissue biopsy for suspected secondary T cell lymphoma.

Late-onset/On-going ICANS

Immune-effector cell associated neurotoxicity (ICANs) is a common complication associated with CAR T cell therapy, affecting up to 80% of patients6. Signs and symptoms can range from headache to delirium and fatal encephalopathy. Whilst ICANs predominantly occurs during the acute in-patient period, it may also present in the third or fourth week following treatment and in rare cases, symptoms may persist for weeks7. There have also been anecdotal reports of ICANs recurring after taper of corticosteroids[8].

Although late onset or recurring ICANs is far less common than its acute presentation, it is important that all healthcare professionals caring for CAR T cell patients at referral centres are aware of the signs and symptoms and action to take.

The main signs and symptoms of ICANs are[6]:

- Encephalopathy
- Tremor
- Aphasia
- Delerium
- Headache (although may not indicate ICANs in every case)
- Confusion
- Poor concentration
- Lethargy
- Agitation
- Cerebral oedema (rare)
- Seizures
- Hallucination

A deterioration in handwriting is also a good indicator of early ICANs. Although any neurological symptom in a CAR T cell patient should be considered to be ICANs until proven otherwise, alternative causes should be considered, including infection, cerebral B-cell disease, iatrogenic causes (particularly opioid toxicity), electrolyte imbalance, or metabolic acidosis.

Patients displaying signs and symptoms of ICANS must be reviewed urgently and discussed as soon as possible with the CAR T cell treatment centre, with rapid access to neurological expertise. The treatment centre may arrange for urgent transfer of the patient where appropriate.

Long term or late onset neurological dysfunction

From the limited long term follow up of CAR T cell patients, long term neurological sequelae following ICANs have been reported, including memory impairment and epilepsy[7].

There have also been case reports of late onset progressive multifocal leukoencephalopathy (PML), presenting up to a year post CAR T cell therapy. Due to limited data, the use of fludarabine as a lymphodepletive agent, plus a predilection for PML amongst lymphoma patients, it is difficult to draw conclusions on the exact role of CAR T cells in the development of PML[9,10].

B-Cell Aplasia

B-Cell aplasia occurs in patients displaying a response to CAR T cell therapy and may persist long term for up to several years. In England, immunoglobulin levels must be monitored monthly and immunoglobulin replacement administered where **national criteria**[2] are met and approval is granted by the Sub-regional Immunoglobulin Panel. For longer term immunoglobulin replacement, transition to home-administered subcutaneous immunoglobulin should be considered. In some cases pneumococcal vaccine may be considered, but it is accepted that a response is unlikely in cases of very low Ig G levels (<3 g/L)[2].

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Graft versus host disease

Although the risk of inducing graft versus host disease (GvHD) in previous allograft recipients is low, relevant patients must be closely monitored. Suspected GvHD must be discussed with the treatment centre, as the effects of immunosuppression on CAR T cell efficacy must be weighed against its benefits.

Psychological support

Many CAR T cell patients experience anxiety and low mood relating to the uncertain prognosis associated with refractory malignancy and the potential for serious, life-threatening adverse effects with CAR T cell therapy. This is often compounded by referral to an unfamiliar treatment centre and team to receive CAR T cell therapy, social isolation and physical distance from normal support networks during and post CAR T cell therapy[1].

All CAR T cell patients should be offered psychological support and counselling where possible. Due to their uncertain prognosis, and the potential to be unable to communicate their wishes in cases of severe CRS or ICANs, patients may find advance care decisions with early involvement of palliative care teams beneficial.

Other late effects include;

- Relapse
- Monitoring for immune-related events
- Impaired fertility and libido
- Psychiatric events

6. References

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APPENDIX 1. Example CAR T Cell Lymphoma Referral Form

Contact Details			
Patient			
Name		Date of Birth	
Phone number		NHS Number	
Address		GP Address	
Next of Kin			
Name		Phone number	
Referring Centre			
Referring Centre		Referring Clinician	
Phone Number (Clinician)		Phone Number (Nurse Specialist)	

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Clinical Details	
Past Medical History	
Condition	Status – ongoing vs resolved
Original Diagnosis	
Date of diagnosis	
Diagnostics	
Staging	
IPI	
CNS-IPI	
MYC/BCL2/BCL6	
Extra-nodal sites	
1st line treatment	
Response to 1st line treatment	
Therapy Related Complications	
Condition	Status – ongoing vs resolved

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First Relapse	
Date of 1st Relapse	
Stage at relapse	
2nd line treatment	
Response to 2nd line treatment	
Second relapse	
Date of 2nd Relapse	
Stage at relapse	
3rd line treatment	
Response to 3rd line treatment	
Third relapse	
Date of 3rd Relapse	
Stage at relapse	
4th line treatment	
Response to 4th line treatment	
Prior Haematopoietic Stem Cell Transplant	
Date of transplant	
Type of transplant – Auto/Allo	
Conditioning	
If Allo – Donor (Sib/MUD/UCB/Haplo)	
If Allo – date immunosuppression ceased	

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Critical Treatment Information	
Date of last chemotherapy and type	
Date of last steroid	
Date of last radiotherapy	
Date of last monoclonal antibody and type	
Date of last GCSF	
Date of last IT chemotherapy and type	
Does patient have central venous access?	
If yes, type of line in-situ;	

Additional Information

CAR T Cell Team Contact Details

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