

Information for patients receiving CAR T cell therapy

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Information for patients receiving CAR T cell therapy



What is CAR T cell therapy

Chimeric antigen receptor T-cell therapy

This is a treatment in which your T cells (a type of white cell that fights infection) are changed in the laboratory so they will attack cancer cells. T cells are taken from your blood by a procedure called apheresis. This is a procedure where your blood is passed through a special machine which divides the cells in your blood into separate components (white blood cells, red blood cells, platelets). The white blood cells are collected and then all other remaining cells and plasma (the liquid part of the blood) are recirculated back to you. This process can take approximately 4-6 hours.

The white blood cells that are collected will then be sent to a manufacturing facility where the T cells will be genetically modified in order to make the special chimeric antigen receptor (CAR) gene into your T cells. They target a protein called CD19 on your tumour cells.

You will receive the CAR T cells as an intravenous (IV) infusion in hospital. The hope is that these genetically modified T cells can then target and kill your tumour cells that have CD19 on their surface.

There is a small possibility you may not receive the cells due to issues with the manufacturing of the product during the manufacturing process itself. If this occurs and your consultant doctor assesses your disease to be stable enough to wait for a second batch to be manufactured, then this will be done. There may be enough of your originally collected white blood cells for this, or you may need to have apheresis repeated.

Collection of your cells

Before you undergo collection (also known as apheresis) of your T cells, you will meet a specialist Apheresis Nurse. The nurse will explain the collection procedure and answer any questions that you may have. They will also organise to take a blood sample from you to test for infections such as HIV, hepatitis and syphilis, which need to be done before your cells can be collected, processed and stored. You will need to consent to these tests as your collection cannot take place without these tests being done.

When and where will my cells be collected?

You will need to attend the Apheresis Unit in the Centre for Clinical Haematology (CCH) at 09:00 on the day we expect your cells to be ready for collection. You will be allocated a date. On this day, you will have a blood test to allow us to input the results into the machine.

How will my cells be collected?

We will place a needle in your arm and blood will be drawn out and into a machine called a cell separator. Here it will be spun and the cells separated out and collected in a bag. The remaining blood will be returned to you through a needle or cannula in your other arm.

The whole process usually takes approximately four to six hours.



What complications might I expect whilst on the machine?

Most people have no problems during the collection and only very rarely do we need to stop the procedure. It is not painful but can be a little uncomfortable. It can also be quite tedious as you are unable to move around.

You may experience some tingling. This often occurs around the mouth initially and is caused by a low calcium level in your blood. This is caused by citric acid that is mixed with your blood while it is in the machine to prevent it from clotting. It is important to inform the nurses if you experience this and it is easily counteracted by giving you some calcium tablets to chew.

Occasionally if the tingling does not improve following the calcium tablets then calcium will be given intravenously (directly into your vein).

Very occasionally patients experience low blood pressure whilst on the machine. This is more likely if you have been taking tablets for high blood pressure so we will usually ask you not to take these on the morning of the procedure. Please check with the apheresis team if you take any other regular medication as these may also need to be paused for the procedure.

Sometimes we have difficulties with the flow of blood from the needle in your arm. This may be a problem if your veins are very small, or if you have had a lot of chemotherapy given through them in the past. Very rarely we have to put a temporary catheter into a large vein in the groin to get around this. This will only remain in place for the collection procedures. If we think that you may need one of these lines the doctor will discuss it with you. If a groin line is required, it will usually mean that you will need to stay in hospital for the line to be cared for and might also require low doses of a blood thinning drug to prevent clots from forming around the line. The line will be removed as soon as possible after we have collected sufficient cells.

Do I need to bring anything with me on the day or make any special arrangements?

You will be attached to the machine for most of the day so you may wish to bring something with you to occupy you during the procedure, such as a book or magazine. We also have some portable DVD players or you can bring your own electronic device as we have free WiFi available. Any such mobile devices are brought in at your own risk and should be used with your own headphones. You are welcome to bring a friend or relative with you to keep you company during the procedure. It is also advisable to wear comfortable clothes and loose or short sleeves that allow easy access to your arms.



You will be able to eat and drink normally during the day. We do provide tea, coffee, biscuits and lunch but feel free to bring in your own snacks too. Please be aware that we cannot disconnect you from the collection machine to go to the toilet until the procedure is finished. If you need the toilet during the procedure the apheresis team can help you use a bedpan or bottle.

You are likely to feel very tired after the procedure and therefore we advise that you do not drive and that you arrange for someone to take you home afterwards. If you need hospital transport at any time, please let us know.

Free parking (car park D only)

If you arrive by car please park in car park D and take the ticket as normal. Give your parking ticket to the Apheresis Team and they can give you an exit ticket so you can receive free parking. Directions can be found on the Trust's website: www.uhb.nhs.uk.

What happens after the collection?

Once the procedure is completed you will be monitored for a short time to ensure you feel well before going home. Your cells will be sent straight to the manufacturing lab for processing.

If we are still unable to collect sufficient cells, despite our best efforts, your doctor may recommend an alternative treatment plan.

Once all the collections have been completed, we will arrange for you to be seen in the outpatient clinic to discuss the reinfusion of the CAR T cells and you will be given an admission date.

Attending for pre transplant work up

Before you are admitted for your CAR-T cells you will need to attend the hospital for a few tests. These tests are a sort of "MOT" for your body and provide information for the doctors to check you are well enough for the planned treatment and that it is safe to continue. These tests are called "pre cell infusion work-up" and usually include a heart scan, lung function test and kidney function test, although these can vary depending on what your consultant advises. You will be sent appointments of when and where to attend for these tests.

CAR T cell therapy

When the tests have been completed and the medical team in charge of your care have checked the results, your consultant will sign a treatment plan for their team to follow when you are admitted to hospital. Please be aware that this process can take a few weeks. Once your treatment plan (also called a treatment protocol) has been signed by your consultant and your cells have been manufactured you will be ready for admission. You will be informed in clinic your dates for chemotherapy and the date for admission to Ward 625 at the New Queen Elizabeth Hospital

The following information is to help you during your stay on the transplant ward. This guidance has been produced to help keep you safe and to make your stay as comfortable as possible. Some of the advice is to help you understand some of the potential side effects that may happen following the infusion of the cells.

What happens next?

1

You will arrive on the day unit on day 1. You will have blood tests and be reviewed by a doctor. We will make arrangements for you to have a PICC line inserted on this day too if you haven't got one in place.

2

Your chemotherapy will start on day 2, it will be administered on the haematology day unit in the Centre for Clinical Haematology according to your individual rota (please ask the nurses if you are unsure).

3

You will receive chemotherapy for either 3 or 4 days depending on your schedule. You will be asked to test your urine at home after each day of chemotherapy – nurses will give you instructions. If you are unwell you may be admitted at any time.

4

On the Sunday after your chemotherapy you will be admitted to the Ward 625. Please call the ward telephone number Sunday morning to confirm time of admission. On arrival to the ward you will have blood tests and be seen by a doctor.

5

Your cells will be given the following day via a drip.
If unwell this may be delayed for a few days.

6

Please be aware that your cells will be defrosted by your bedside. You will receive intravenous fluids before and after the infusion of cells and given an antihistamine called piriton to stop any allergic reactions.

7

You will be monitored daily during your recovery time (weight, blood pressure, temperature, blood tests, nurse checks, doctor's rounds etc.).

8

You will be in hospital for at least 10 days.

9

One of the clinical nurse specialist nurses will visit you on the ward during your stay.

10

You will have to stay somewhere close to the hospital for 4 weeks after discharge, within a 1 hour commute. If you live far away you will need to arrange accommodation. You will need someone to be with you at all times for 4 weeks following infusion of CAR T.

11

Following discharge you will receive medical review at the QE initially three times per week for first week then twice for the next week and then weekly for until the doctor decides to extend the time between appointments.

12

If you experience any complications following cell infusion, you will only be discharged when your doctor feels you have recovered.

13

You will not be able to drive for 8 weeks following infusion of CAR T.

What are the side effects of treatment?

1. Cytokine release syndrome (CRS) -Medical emergency

Cytokine release syndrome is an immune system response to the cells that have been infused into your body. This makes the body release a large amount of certain proteins called cytokines that can make you feel very unwell.

Signs to look out for

- fever (38°C or higher)
- difficulty breathing
- chills or shaking chills
- confusion
- dizziness or light-headedness
- severe nausea, vomiting or diarrhoea
- fast or irregular heartbeat

Management

You may have to attend the intensive care unit if your doctor feels you need closer observation.

Tocilizumab

This is a special drug that can help with the side effects caused by the cytokine release syndrome.

2. Neurotoxicity

The treatment can cause problems with your nervous system. Before treatment starts and following infusion of cells, the medical team will ask you to write a short sentence to assess your handwriting as part of the neurological tests.

Signs to look out for

- Confusion
- Drowsiness
- Finding it hard to communicate
- Seizure

3. The treatment lowers your B cells

B Cells are responsible for producing antibodies that kill infections. The B Cells are killed by CAR-T cells making you vulnerable to infection.

Management

Immunoglobulin is an intravenous therapy to provide the necessary antibodies to help you fight infection until your B cells recover.

Welcome to the Haematology and Stem Cell Transplant Ward

Ward 625

Address	Ward 625 – 6th Floor New Queen Elizabeth Hospital Birmingham Mindelsohn Way Edgbaston, Birmingham B15 2GW
Ward Manager	Kate Gooding
Telephone	0121 371 6250
Visiting Times	11:00-20:00
Fresh flowers	Not permitted
Mobile phones and devices	Permitted at own risk
Bedside radio	Free where available
Bedside landline phone	Available with pre-paid card
Bedside TV	Available with pre-paid card
Communal TV	Free
Wi-Fi	Free (email required)
Accommodation	4 Bedded Bays and Isolation Rooms (allocation depending on)

Accommodation

The ward is made up of some bays of 4 patients and some single isolation rooms. The whole ward is air filtered to minimise risk of infection and you will notice there are two doors at the entrance to keep the filtered air inside the ward. When you are admitted you may be allocated a bed in the 4 bedded bays and then will usually be moved into an isolation room after your treatment when your blood tests show your immune system is low. However, please be aware that rooms are allocated based on the clinical needs of current patients. Visitors are not permitted to stay with patients overnight unless there are special circumstances. If you have any concerns about your accommodation or privacy please discuss them with the ward staff.

Diet

It is important to try and keep your nutritional intake as good as possible whilst you are having your treatment, however you can have side effects which may affect your appetite. If you are struggling to eat your meals, please discuss this with the nursing staff as there are alternative menu's and lots of appetising hot and cold snacks available at any time. If appropriate, you can be referred to a dietician who can assess your dietary needs and give you tailored advice and supplements.

Visiting

You may find it beneficial to have visitors whilst you are in hospital, as support from family and friends are a great way to keep positive. Even if you are in an isolation room whilst your immune system is low, it is safe for you to have visitors as long as they follow this guidance:

- They have not had a recent infection or recently been in contact with someone with a contagious infection
- They are not currently unwell with fevers, flu, diarrhoea or vomiting
- They wash their hands on arrival and before they leave the ward
- They remove their outdoor coats and put on a plastic apron before entering an isolation room (gloves/masks are not required)
- There are no more than 3 visitors per bed space at any one time
- They visit between 11am and 8pm (visits outside of these times are at the discretion of the nurse in charge)
- Children may visit when accompanied and supervised by a responsible adult at all times. There is no age restriction however they should not visit if they are unwell. Please check with the nurse in charge if very young children or children who have recently been vaccinated would like to visit.
- Please be aware visitors may be asked to wait outside the room at times in order to maintain patient dignity/confidentiality.

Flowers

Unfortunately fresh flowers are not permitted on the ward due to infection risk.

Phone calls

Mobile phones are permitted on the ward but please be aware the signal is variable. There are bedside payment phones attached to the TV sets in some areas. If family and friends are calling the ward directly for information about your recovery, it is best to nominate one person to do this and pass on updates. Please be aware of other patients' privacy and dignity when making phone calls in communal areas.

Entertainment

You will normally be in hospital for at least 2 weeks and so it is a good idea to bring some entertainment with you such as books, magazines, puzzles, games, laptop or tablet. There are televisions in some of the rooms on the ward with free access to radio however payment is required to access the television channels. Top up cards for the televisions can be bought from the payment machines in the hospital corridor. There is free WiFi supplied by the Queen Elizabeth Hospital Charity, which can be accessed by entering an email address and agreeing to terms of use. Unfortunately nursing staff are not able to help with technical issues around WiFi usage. If you would like to bring a tablet or laptop to use during your stay this will be at your own risk. There is also a day room with a free communal television which is safe to use unless your immune system is low.

Hygiene/Clothing/Mobility

It is a good idea to bring comfortable day clothes and separate pyjamas to wear in hospital. You should also bring some comfortable footwear i.e. slippers. To help to give your day some structure it is advisable to have a wash and get dressed into your day clothes each day. If you are feeling very tired or weak please ask the nursing staff for help with this, they will be happy to help you at any time, even if they appear busy! It is advisable to use the hospital towels and linen rather than your own, as they are washed every day at a very high temperature to kill bacteria. It is also advisable to use the disposable wash cloths and shower gel/body wash rather than your own flannel and bar of soap as they can grow bacteria if left out and re-used. You should send your day clothes and pyjamas home regularly to be washed or use the hospital pyjamas.

It is good to try and to stay physically active whilst you are in hospital, even if you have been advised to stay in your room. You can sit out of bed and do gentle exercises such as a short walk around the room at least a few times per day; even getting up to the bathroom will help your recovery. If you are able to, you could walk to the day room or along the corridor, but please check with the nursing team before you do. If necessary you can be referred to the physiotherapy or occupational therapy teams to help you with your mobility.

Medical/Nursing Care

You may be asked by the nursing team to complete a fluid balance chart. This means recording how much fluid you have drunk and how much urine you have passed each day so that the doctors can make sure you do not get dehydrated. The nurses will explain how to complete the chart but if you have any questions please ask.

There are usually four medication rounds each day, however each patient will be prescribed different medicines at different times. If you feel you need any of your medication in between these times please speak to the doctors and nurses looking after you.

Your blood pressure, temperature and pulse will be checked regularly; these are called 'observations' or 'obs'. If you are unwell or at risk of infection the nursing team may need to check your observations more frequently including overnight. You will also be asked some questions to test your neurological condition such as "What hospital are you in?, What is the year, count backwards from 20?".

During your stay you may require intravenous medication given as a drip via a line in your arm. These are given using electronic pumps which will beep when the drip needs to be changed. Please let the nursing staff know if you think there is a problem with your pump or it has finished and they will check it as soon as they are able.

Feeling unwell/infections

Every person is different and responds to treatment in a different way. Some people may feel unwell and need to rest but others may feel able to do a bit more. You may want visitors to come every day or some days you may want to rest instead. It is important to tell the hospital team and your friends and family how you are feeling so that they can support you whilst you recover. You must report any changes in your symptoms to your medical team immediately, however small and insignificant they may seem. This allows the medical team to correct any problems before they worsen. The doctors will advise you about the medication and interventions you may need during your stay in hospital. There will be a daily ward round where the consultant and the Registrar Doctor visits each patient to assess them and decide if any additional treatment is required.

Emotional Support

Being in hospital can be hard, but many of the difficulties you encounter can be overcome with the help of the nursing and medical team who are keen to make your stay as comfortable as possible and who will try to deal with any concerns. However if you wish we can arrange for you to talk to a professional trained in this area to explore your feelings and help you cope. There is a Cancer Information and Support Services Manager based in the Patrick Room in the Cancer Centre who provides signposting to such services (Tel: 0121 371 3539).

Contact Information (pre admission)

Apheresis Team: 0121 371 7820 or 7821

(for any enquiries prior to admission to hospital • Monday-Friday 8am-6pm)

Ward 625: 0121 371 6251 or 6252

Emergency CAR-T contact information

Tel: 07920 253978