

## **Managing patients on monoclonal antibody therapies – an information pack for hospital transfusion laboratories, transfusion practitioners & Haematology clinical teams**

### **Summary**

Treatments which include monoclonal antibody-based therapies are being identified and developed for use in clinical practice, in the treatment of patients with haematological malignancies. Recent guidance from the National Institute of Health and Care Excellence (NICE) has supported the use of the monoclonal anti-CD38 therapy, Daratumumab (Darzalex) in patients with relapsed or refractory Multiple Myeloma (MM). Other monoclonal therapies currently at clinical trial stage include Isatuximab, another anti-CD38 therapy for the treatment of relapsed or refractory MM patients, and an anti-CD47 (Hu5F9-G4), for use in patients with relapsed or refractory Acute Myeloid Leukaemia (AML) or Myelodysplastic Syndrome (MDS). (CAMELLIA Trial).

These therapies have shown promising results in clinical trials, and their routine use in clinical practice is expected to increase.

These therapies however, have the potential to adversely interfere with serological investigations and compatibility testing in the blood bank, potentially causing unnecessary delays in providing blood components for transfusion. This means that there may be a potential for delay in treatment of these patients, many of whom are transfusion dependent. Different monoclonal antibody therapies may affect serological testing methods in a variety of ways, and the monoclonal antibody-induced reactivity can persist for up to 6 months after the last treatment infusion.

The following information and accompanying slide pack is intended to guide hospital transfusion laboratories, transfusion practitioners & Haematology clinical teams in their management of patients on monoclonal antibody therapies.

## **Testing Procedure**

The following testing protocols should be undertaken in the hospital blood bank, according to local procedures or referred to the nearest Red Cell Immunohaematology (RCI) Laboratory for testing, as required. (See the April 2017 addendum to the BSH Guideline for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories for details)

**IMPORTANT: Please make the hospital blood bank and / or the RCI laboratory aware that the patient is about to start, or has already started monoclonal antibody therapy.**

**For patients being considered for monoclonal antibody therapies (Anti-CD38 therapies Daratumumab / Darzalex / Isatuximab / Anti-CD47 CAMELLIA trial)**

1. Baseline ABO and D group (follow local policy for requirement of confirmatory sample rule for ABO and D group)
2. Antibody screen, and antibody identification, if required.
3. Direct Antiglobulin Test (DAT)
4. Extended phenotyping/genotyping for C, c, E, e, K, (k if K+), MNSs, Jk<sup>a</sup>, Jk<sup>b</sup>, Fy<sup>a</sup> and Fy<sup>b</sup> groups within local hospitals or referred to the nearest NHSBT RCI laboratory if required.  
(genotyping to be used if the patient has been recently transfused, < 1month ago)

**For patients who are already on anti-CD38 therapies (Daratumumab / Darzalex / Isatuximab)**

1. ABO and D typing as per normal method
2. Antibody screening, and antibody identification if required, using a strategy to avoid the effect of anti-CD38, e.g. reagent cells treated with 0.2M Dithiothreitol (DTT).
3. Red cells should be matched for Rh and K as well as for any alloantibodies

**For patients who are already on anti-CD47 therapies (CAMELLIA Trial)**

1. ABO and D typing as per normal method. If the ABO group cannot be concluded, group O red cells may be required for transfusion
2. In patients who have a panagglutinin in serological testing and are DAT positive, adsorption studies can allow satisfactory antibody detection / identification in many cases

## **Communication**

A breakdown in communication between patients, clinical teams and laboratory staff can lead to unnecessary delays in providing blood components for transfusion, and may have an adverse impact on patient care.

### **Patients**

Patients who are about to begin monoclonal antibody therapies should be provided with a card alerting the clinical team to their condition and treatment. An example of a patient card is given in the accompanying slide pack. This card should be shown to clinical staff at any hospital that the patient receives treatment at, should the patient be admitted at an alternative location to the haematology clinic. Patients should carry their patient card for up to 6 months after their treatment has ended because of the persistence of monoclonal antibody-induced reactivity and interference in blood bank testing.

### **Clinical teams**

It is vitally important that the hospital blood bank and / or the nearest RCI laboratory is informed that the patient is about to start, or has already started a monoclonal antibody therapy. Details of the monoclonal antibody therapy may be indicated in the special requirements section on the blood transfusion request form.

### **Laboratory staff**

Patients should be investigated according to the testing procedure above. If the patient has previously been referred to a regional RCI laboratory for investigation, specific patient reports and further information regarding serological testing performed at NHSBT RCI laboratories can be found on the online NHSBT Sp-ICE browser.

## **Planning of transfusion**

The following recommendations have been made in the April 2017 addendum to the BSH guidelines Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories, Available at:

<https://www.b-s-h.org.uk/media/15725/monoclonal-antibodies-addendum.pdf>

**Red cells should be matched for ABO, Rh and K as well as for any alloantibodies.**

**K negative red cells should be provided for patients unless they are known to be K positive; in this case, k negative red cells should be provided on the rare occasion that the patient is K+k-**

Transfusions for patients on monoclonal antibody therapies should be planned during routine hours, and should allow sufficient time for extended serological testing and crossmatching, once received at a regional NHSBT RCI laboratory.

Out of hours, investigations and crossmatching for patients on monoclonal antibody therapies will not be routinely performed by NHSBT RCI staff, except in an emergency. Please contact the regional RCI laboratory for advice in this circumstance.

## **Essential Information**

An accompanying slide pack has been produced by NHSBT to aid hospital transfusion laboratories, transfusion practitioners & Haematology clinical teams in the management of these patients.

The [slide pack](#) is published in the Clinical guidelines section on the NHSBT Hospital and Sciences website.