

Change Notification for the UK Blood Transfusion Services

Date of Issue: 26 November 2024

Implementation: to be determined by each Service

No. 49 – 2024

Monoclonal Antibody Therapies

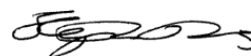
This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue - Deceased Donors	TL-DSG Tissue - Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Autoimmune Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
2. Hypercholesterolaemia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
3. Monoclonal antibody therapy and other Biological Modalities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
4. Psoriasis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>



Dr Angus Wells

Chair of Standing Advisory Committee on Care & Selection of Donors (SACCSO)



Dr Stephen Thomas

Professional Director of JPAC

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text

«inserted text»

~~deleted text~~

1. Changes apply to the **Whole Blood and Components DSG**

Autoimmune Disease

(revised entry)

<i>Obligatory</i>	<p>Must not donate if:</p> <p>a) The donor has needed treatment «with steroids or conventional disease modifying antirheumatic drugs» to suppress the condition in the last 12 months.</p> <p>«b) The donor has needed treatment with monoclonal antibody therapy or other biologic disease modifying antirheumatic drugs to suppress the condition in the last 6 months.»</p> <p>«c)» b) The cardiovascular system is involved.</p> <p>«d)» e) The donor has ongoing lung disease or renal impairment due to their condition.</p>
<i>Discretionary</i>	<p>a) If the donor:</p> <ul style="list-style-type: none"> • has been established on a stable maintenance treatment for an Autoimmune Disease with only one of the following drugs: Methotrexate, Sulfasalazine, Hydroxychloroquine or Azathioprine, and • the dose of the drug has not increased in the previous 6 months, and • the donor is well, <p>accept.</p> <p>b) If there is any uncertainty about the diagnosis or the nature of treatment, refer to a DCSO.</p>
<i>See</i>	Is there a specific A-Z index entry for the condition you are assessing?
<i>See if Relevant</i>	<p><u>Cardiovascular Disease</u></p> <p><u>Disabled Donor</u></p> <p>«Drug Index – Drugs and Platelet Donation»</p> <p>Drug Index – preparations which may affect platelet function</p> <p>«Fertility»</p> <p><u>Inflammatory Bowel Disease</u></p> <p><u>Liver Disease</u></p> <p><u>Monoclonal antibody therapy and other Biological Modalities</u></p> <p><u>Nonsteroidal Anti-inflammatory Drugs</u></p> <p><u>Skin Disease</u></p> <p><u>Steroid Therapy</u></p> <p><u>Thrombosis and Thrombophilia</u></p> <p>Trying to Conceive</p> <p>If treated with transfusion, immunoglobulin, plasma exchange or filtration:</p> <p><u>Transfusion</u></p>
<i>Additional Information</i>	Conventional systemic Disease Modifying Antirheumatic drugs (csDMARDs) are viewed as disease-modifying drugs. They include Methotrexate, Sulfasalazine, Hydroxychloroquine and Azathioprine. Sulfasalazine and Hydroxychloroquine have limited effect on the immune system. If used for maintenance treatment, Methotrexate

	<p>and Azathioprine are usually given at lower doses which do not cause a significant degree of immunosuppression.</p> <p>If the donor is taking higher dose Methotrexate or Azathioprine, they should not be accepted. If there is uncertainty about the dose refer to the DCSO for assessment. Further information on these drugs and immunosuppression can be found in 'The Green Book: Immunisation against Infectious Disease' (available at www.gov.uk).</p> <p>Nonsteroidal anti-inflammatory drugs do not suppress the donor's immune system.</p> <p>Physical therapies such as physiotherapy and hydrotherapy are not considered treatments to suppress the condition.</p> <p>Autoimmune disease can cause problems such as infertility and thrombosis (antiphospholipid or Hughes' syndrome).</p> <p>Some autoimmune conditions can permanently damage the cardiovascular system. If this is known to have happened, the person should not donate as they are more likely to have a serious adverse event.</p>
<p><i>Reason for Change</i></p>	<p>«The obligatory criteria have been expanded to specify the deferral period required depending on the type of treatment.»</p> <p>The acceptance criteria for donors taking csDMARDS has been clarified and extended. The See if Relevant section has been expanded.</p>
<p><i>Donor Information</i></p>	<p>If you wish to obtain more information regarding a personal medical issue, please contact your National Help Line.</p> <p>Please do not contact this web site for personal medical queries, as we are not in a position to provide individual answers.</p>

2. Changes apply to the **Whole Blood and Components DSG**

Hypercholesterolaemia

(revised entry)

<p><i>Obligatory</i></p>	<p>Must not donate if:</p> <p>a) Has caused symptomatic disease.</p> <p>b) Associated with cardiovascular disease.</p> <p>c) Is currently being treated with systemic monoclonal antibody therapy e.g. Evolocumab (Repatha®), Alirocumab (Praluent®).</p> <p>d) Has been treated with Evolocumab (Repatha®) or Alirocumab (Praluent®) in the last 4 months.</p> <p>e) Has been treated with any other monoclonal antibody therapy «or biologic treatments» in the last «6» 12 months.</p>
<p><i>Discretionary</i></p>	<p>a) If has not led to symptomatic disease, even if currently on treatment (other than monoclonal antibody therapy), accept.</p> <p>b) If it is more than 4 months since cessation of treatment with Evolocumab (Repatha®) or Alirocumab (Praluent®), accept.</p> <p>c) If it is more than «6» 12 months since cessation of treatment with any other monoclonal antibody «therapy or biologic» treatment, accept.</p>
<p><i>See if Relevant</i></p>	<p><u>Cardiovascular Disease</u> <u>Cerebrovascular Disease and Intracranial Haemorrhage</u></p>
<p><i>Additional Information</i></p>	<p>Hypercholesterolaemia occurs when the level of cholesterol in the blood is outside of the reference range for the donor's age and sex. Usually this is managed by modifying the diet and often by the use of oral drugs.</p> <p>Treatment may be with monoclonal antibodies which are administered by subcutaneous injection; these can affect the immune system making individuals more susceptible to infections and/or masking the usual symptoms of an infection, thus increasing the chance that a donor may unknowingly have an infection present at the time of donation. This effect may last until the drug is cleared from the body. Observing a deferral period after cessation of treatment with monoclonal antibody therapy will minimise this risk. The deferral periods advised take into account the characteristics of these drugs, including the time it takes for them to be cleared once treatment stops.</p> <p>High levels of cholesterol are of themselves not a reason to defer a donor. If the hypercholesterolaemia has led to symptomatic disease, such as cardiovascular problems or transient visual or other neurological problems the donor should not be accepted, even if their cholesterol has returned to normal levels.</p> <p>It is important to ensure that donors on treatment for hypercholesterolaemia do not have any associated cardiovascular disease.</p>

<p><i>Reason for Change</i></p>	<p>«The deferral period following treatment with other monoclonal antibody therapy has been modified to be consistent with the Monoclonal antibody therapy and other Biological Modalities entry. Reference to other biologic treatments has also been included for the same reason.»</p> <p>Link updated from 'Central Nervous System Disease' to 'Cerebrovascular Disease and Intracranial Haemorrhage' in the 'See if Relevant' section.</p>
<p><i>Donor Information</i></p>	<p>If you wish to obtain more information regarding a personal medical issue, please contact your National Help Line.</p> <p>Please do not contact this web site for personal medical queries, as we are not in a position to provide individual answers.</p>

3. Changes apply to the **Whole Blood and Components DSG**

Monoclonal antibody therapy and other Biological Modalities (revised entry)

<i>Includes</i>	Systemic treatment with monoclonal antibody (MAb) treatments.
<i>Obligatory</i>	Must not donate.
<i>Discretionary</i>	<p>a) If an individual monoclonal antibody treatment is listed in the entry for the underlying condition, apply guidance as per that entry.</p> <p>b) If the underlying condition does not preclude donation, and it is more than 6 months from last treatment, accept.</p>
<i>See</i>	Is there is a specific A-Z index entry for the treatment and/or condition you are concerned about?
<i>See if Relevant</i>	<p>«Asthma»</p> <p>Autoimmune Disease</p> <p>Clinical Trials</p> <p>«Dermatitis»</p> <p>Eye Disease</p> <p>Hypercholesterolemia</p> <p>«Migraine»</p> <p>Osteopenia</p> <p>«Psoriasis»</p>
<i>Additional Information</i>	<p>«The use of monoclonal antibody and other biological therapies continues to expand. Care should be taken to understand the type of treatment and the indication, which may not be included in the ‘See if Relevant’ section.»</p> <p>Current scientific literature does not provide conclusive evidence to reject concerns that individuals on these treatments are more prone to infection. Until further clarity is provided in the literature, donors on these medications are withdrawn, unless otherwise stated.</p>
<i>Reason for Change</i>	<p>«Links to conditions that are currently commonly treated with monoclonal antibody therapies have been added to the ‘See if Relevant’ section, with reference to the expansion in types of treatment and use of these treatments within the ‘Additional Information’ section.»</p> <p><i>This is a new entry.</i></p>

4. Changes apply to the **Whole Blood and Components DSG**

Psoriasis

(revised entry)

<i>Includes</i>	Psoriatic Arthritis
<i>Obligatory</i>	<p>Must not donate if:</p> <p>a) Has ever taken etretinate (Tigason®).</p> <p>b) Less than 36 months from the last dose of acitretin (Neotigason®).</p> <p>c) Less than 6 months from the last dose of any treatment that may affect the immune system.</p> <p>d) Generalised or severe.</p> <p>e) There is secondary infection.</p>
<i>Discretionary</i>	<p>a) If mild, the venepuncture site is unaffected and only using topical treatment, accept.</p> <p>b) If the donor:</p> <ul style="list-style-type: none"> • has been established on oral treatment for their disease with only one of the following drugs: Methotrexate, Sulfasalazine, Hydroxychloroquine or Azathioprine, and • their disease is controlled by medication, and • «the dose of the drug has not increased in the previous 6 months, and» • the venepuncture site is not affected, and • the donor is well, <p>accept.</p> <p>c) If the donor:</p> <ul style="list-style-type: none"> • is receiving PUVA or UVA therapy for their skin disease, and • their disease is controlled, and • the venepuncture site is not affected, and • the donor is well, <p>accept.</p>
<i>See if Relevant</i>	<p><u>Autoimmune Disease</u></p> <p>«Monoclonal antibody therapy and other Biological Modalities»</p> <p><u>Steroid Therapy</u></p>
<i>Additional Information</i>	<p>Psoriasis is primarily a skin condition caused by an autoimmune process. Sometimes the disease is treated with powerful drugs and/or ultraviolet radiation to suppress the underlying autoimmune process. This may be with treatment with PUVA, methotrexate, ciclosporin, hydroxycarbamide etc. and this may alter the body's defence mechanisms to infection.</p>

	<p>Etretinate (Tigason®) and acitretin (Neotigason®) can cause birth defects in babies exposed to them while inside the womb. It is important to allow time for the drug to be cleared from the blood of a donor. It takes longer to clear some drugs than others.</p>
<i>Reason for Change</i>	<p>«The text has been further updated to ensure consistency with other DSG references to immunosuppression.»</p> <p>A discretion to accept donors on oral medication has been added and the text has been updated to ensure consistency with other DSG references to immunosuppression.</p>
<i>Donor Information</i>	<p>If you wish to obtain more information regarding a personal medical issue, please contact your <u>National Help Line</u>.</p> <p>Please do not contact this web site for personal medical queries, as we are not in a position to provide individual answers.</p>