

Change Notification for the UK Blood and Tissue Services

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Implementation To be determined by each Service

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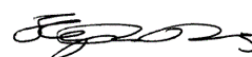
Immunosuppression and monoclonal antibody treatments

Content changed	Type of change	Guidelines affected
1 Monoclonal antibody therapy and other biological modalities	New entry	Tissue (deceased) Tissue (live)
2 Immunosuppression	Updated entry	Tissue (deceased)
3 Immunosuppression	Updated entry	Tissue (live)
4 Steroid therapy	Updated entry	Tissue (deceased)
5 Steroid therapy	Updated entry	Tissue (live)
6 'See if relevant' links	Updated hyperlinks	Tissue (deceased) Tissue (live)



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Note: this document indicates **inserted** and **deleted** text. This formatting will not apply in the published text.

1. Monoclonal antibody therapy and other biological modalities

Guidelines affected

Reason for change

Tissue (deceased)

This is a new entry.

Tissue (live)

Essential information

Obligatory

See: is there an entry for the condition?

Discuss with a Designated Clinical Support Officer if:

The donor is being treated with monoclonal antibodies, to consider whether the treatment has an impact on the quality and safety of the donated tissue and/or has an immunosuppressive effect.

Supporting information

See if relevant

- Autoimmune disease
- Immunosuppression and immunodeficiency

Additional information

The use of monoclonal antibodies 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 above.

'Biological modalities' and 'biologics' are terms used for a broad class of therapeutics that are derived from or rely on living organisms, cellular components or genetic material.

In addition to monoclonal antibodies, biological modalities include:

- nucleic acids (e.g. gene therapies)
- cellular therapies (e.g. CAR-T cells)
- proteins and peptides used to regulate metabolic and bodily functions
- targeted degraders used to induce the elimination of disease-causing proteins

Further types of biological modality are in development (e.g. antibody-drug conjugates to deliver therapies to specific cells).

Consideration needs to be given as to whether the treatment the donor is on may be impacting the quality of the donated tissue (as long as the underlying condition is not itself a reason for deferral) and to assess whether the treatment may be leading to immunosuppression in the donor, in which case refer to the 'Immunosuppression and immunodeficiency' entry.

2. Immunosuppression and immunodeficiency

Guidelines affected	Reason for change
Tissue (deceased)	The entry has been renamed from 'Immunosuppression' to 'Immunosuppression and immunodeficiency'. Discretionary guidance has been reformatted to improve readability, and it has been clarified that all types of immunodeficiency need to be considered, not just those secondary to treatment. 'See if relevant' links have been updated.

Essential information

Obligatory	Must not donate if: Immunosuppressed <u>or otherwise immunodeficient</u>.
Discretionary	1. Donors who are on immunosuppressive therapy <u>or are otherwise immunodeficient</u> (if the underlying condition is not a contraindication): If ALL the following criteria are met: a. The quality of the tissue being donated is not affected, and b. NAT testing is performed for HIV, HCV and HBV in addition to mandatory antibody tests and shown to be negative, and c. The tissue being donated is not affected by severe local infection and there is no evidence of systemic infection. <u>OR (for corneas only): In cases of bacterial infection (where there is no active ocular infection) and the corneas are to be stored by organ culture.</u> (OR) For corneas only: In cases of bacterial infection (where there is no active ocular infection) and the corneas are to be stored by organ culture. Donor may be accepted, subject to a documented risk assessment. See Additional information below. 2. Donors with recovered immunodeficiency: Refer to a Designated Clinical Support Officer.

Supporting information

See if relevant	• Autoimmune disease • Immunoglobulin therapy • Infection, acute • Infection, chronic • Monoclonal antibody therapy and other biological modalities • Steroid therapy
Additional information	The Human Tissue (Quality and Safety for Human Application) Regulations, 2007, as amended, specifies a range of allogeneic donor deferral criteria. These are set out in Annex A of the Human Tissue Authority (HTA) 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment'. Regulatory requirements for donor testing are set out in Annex B of the Guide and specify the requirement for serological testing irrespective of NAT testing. Annex A, part 1.1.8 states: "Indications that test results of donor blood samples will be invalid due to...treatment with immunosuppressive agents." Whilst antibody detection relies on the host response, antigen and molecular assays directly detect components of the infectious agent. Assays which directly detect the virus are not affected adversely by immunosuppression and are appropriate to use to support decision making in this situation. This is permitted under the SaBTO 'Guidance on the microbiological safety of human organs, tissues and cells used in transplantation' (2020). The regulatory requirement, as set out in the HTA Guide is as follows: Para 85: "Donors must be excluded from donation if any of the criteria in Annex A apply unless donation is justified on the basis of a documented risk assessment approved by the Designated Individual (DI)." To comply with the regulatory requirement, Tissue Establishments (TEs) must ensure that they have a current documented risk assessment that covers all the tissues in question before authorising a donation for clinical use on the basis of the Discretionary criteria set out above. Donors on immunosuppression or who are otherwise immunodeficient may be prone to an increased risk of infection, and symptoms may be masked by immunosuppressive medication. All available information, including any medication (e.g. monoclonal antibodies, immunoglobulins), must be carefully assessed as part of donor evaluation and expert opinion sought where required.
Regulatory information	This advice is a requirement of the EU Tissue and Cells Directive.

3. Immunosuppression and immunodeficiency

Guidelines affected	Reason for change
Tissue (live)	The entry has been renamed from 'Immunosuppression' to 'Immunosuppression and immunodeficiency'. 'Obligatory' and 'Discretionary' guidance has been reorganised. 'See if relevant' links have been updated.

Essential information

Obligatory	Must not donate if: Immunosuppressed <u>or otherwise immunodeficient</u>. Donors with recovered immunodeficiency: Refer to a Designated Clinical Support Officer.
<u>Discretionary</u>	<u>Donors with recovered immunodeficiency:</u> <u>Refer to a Designated Clinical Support Officer.</u>

Supporting information

See if relevant	• Autoimmune disease • Immunoglobulin therapy • <u>Monoclonal antibody therapy and other biological modalities</u> • Steroid therapy
Regulatory information	This advice is a requirement of the EU Tissue and Cells Directive.

4. Steroid therapy

Guidelines affected	Reason for change
Tissue (deceased)	Additional information updated to provide guidance on how to assess the area of skin being treated with steroids. Link to 'Monoclonal antibody therapy and other biological modalities' entry added.

Essential information

Obligatory	Discuss with a Designated Clinical Support Officer if: Has been regularly taking steroid tablets, injections or enemas, or applying creams over large areas. For information on other situations where steroid therapy may be acceptable, see 'Immunosuppression and immunodeficiency'.
Discretionary	1. If occasional use of creams over small areas of skin (<9% of body surface area) for minor skin complaints, accept. 2. If using steroid inhalers for prophylaxis, accept. 3. Cornea only: If corneas are stored in organ culture and in the absence of other contraindications, accept. See Additional information below.

Supporting information

See if relevant	• Autoimmune disease • Eye disease • Immunosuppression and immunodeficiency • Infection, acute • Infection, chronic • Monoclonal antibody therapy and other biological modalities • Skin disease • Tissue and cell allograft recipients
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Additional information	Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation. For further information, refer to 'Immunosuppression and immunodeficiency'. <u>A small area of skin is defined as <9% (Wallace Rule of Nines). For guidance, 1% is equal to the area of the closed digits and palm of the donor's hand, and 9% is equal to the total area of one arm. Any area >9% is defined as large.</u> The underlying condition requiring steroid treatment should always be taken into consideration. Eye donors receiving steroid treatment (e.g. steroid eye drops) should be evaluated on a case-by-case basis, taking into consideration the indication for treatment as well as any possible side effects. Relevant clinical records, especially ophthalmology records, should be reviewed.
Regulatory information	Part of this advice is a requirement of the EU Tissue and Cells Directive.

5. Steroid therapy

Guidelines affected	Reason for change
Tissue (live)	Additional information updated to provide guidance on how to assess the area of skin being treated with steroids. Removal of deferral if donor required treatment with steroids in the 7 days prior to donation for reasons of allergy. Link to 'Immunosuppression and immunodeficiency' and 'Monoclonal antibodies and other biological modalities' entries added.

Essential information

Obligatory	Must not donate if: 1. Regularly Taking steroid tablets, injections or enemas, or applying creams over large areas. 2. The donor has needed treatment to suppress an autoimmune condition in the last 12 months. 3. Less than 7 days after completing a course of oral or injected steroids for disorders associated with allergy.
Discretionary	- If occasional use of creams over small areas of skin (<u><9% of body surface area</u>) for minor skin complaints, accept. - If using steroid inhalers for prophylaxis, accept. <u>If using steroid eye drops, nasal spray or ear drops for control of allergic symptoms, accept.</u> <u>Discuss with a Designated Clinical Support Officer if:</u> <u>Has been taking steroid tablets, injections or enemas, or applying creams over large areas.</u> <u>For information on other situations where steroid therapy may be acceptable, see 'Immunosuppression and immunodeficiency'.</u>

Supporting information

See if relevant	- Autoimmune disease <u>Immunosuppression and immunodeficiency</u>
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	• Monoclonal antibody therapy and other biological modalities • Skin disease • Tissue and cell allograft recipients
Additional information	Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation. A small area of skin is defined as <9% (Wallace Rule of Nines). For guidance, 1% is equal to the area of the closed digits and palm of the donor's hand, and 9% is equal to the total area of one arm. Any area >9% is defined as large.
Regulatory information	Part of this advice is a requirement of the EU Tissue and Cells Directive.

6. 'See if relevant' links

Guidelines affected	Reason for change
See below	Update of 'See if relevant' links due to the renaming of the 'Immunosuppression' entry as 'Immunosuppression and immunodeficiency'.

For each entry below, the 'See if relevant' links will be updated as shown

Guidelines affected	Entry	Link to be updated
Tissue (deceased)	Autoimmune disease	Immunosuppression and immunodeficiency
Tissue (deceased)	Eye disease	Immunosuppression and immunodeficiency
Tissue (deceased)	Immune thrombocytopenia	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Kidney disease	Immunosuppression and immunodeficiency
Tissue (deceased)	Malignancy	Immunosuppression and immunodeficiency
Tissue (deceased)	Psoriasis	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Radiation therapy	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Recipients of normal human immunoglobulin	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Systemic lupus erythematosus (SLE)	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Tissue and cell allograft recipients	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Transfusion	Immunosuppression and immunodeficiency
Tissue (live)		
Tissue (deceased)	Vasculitis	Immunosuppression and immunodeficiency