

Issued by JPAC: 29 April 2021

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 08 - 2021

Hypercholesterolaemia

These changes apply to the Whole Blood and Components Donor Selection Guidelines

Please amend the following sections in this entry:

Obligatory: Must not donate if:

- a) Has caused symptomatic disease.
- b) Associated with cardiovascular disease.
- c) Is currently being treated with systemic monoclonal antibody therapy e.g. Evolocumab (Repatha®), Alirocumab (Praluent®).
- d) Has been treated with Evolocumab (Repatha®) or Alirocumab (Praluent®) in the last 4 months.
- e) Has been treated with any other monoclonal antibody therapy in the last 12 months.

Discretionary:

- a) If has not led to symptomatic disease, even if currently on treatment (other than monoclonal antibody therapy), accept.
- b) If it is more than 4 months since cessation of treatment with Evolocumab (Repatha®) or Alirocumab (Praluent®), accept.
- c) If it is more than 12 months since cessation of treatment with any other monoclonal antibody treatment, accept.

See if Relevant:

Cardiovascular Disease
Central Nervous System Disease

Additional Information:

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.

Treatment may be with monoclonal antibodies which are administered by subcutaneous injection; these can affect the immune system making

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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.

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.

It is important to ensure that donors on treatment for hypercholesterolaemia do not have any associated cardiovascular disease.

Reason for change: ~~A link has been added to 'Central Nervous System Disease'~~
The addition of an obligatory deferral for donors treated with systemic monoclonal antibody therapy for hypercholesterolaemia.

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