

Autologous Serum Eyedrops Service

Purpose

To achieve consistency of service and product with respect to provision of Autologous Serum Eyedrops by NHS Blood and Transplant (NHSBT).

Requirements

Part 1 – Service specification

- 1.1 **Patient referral.** Referrals of patients for the Autologous Serum Eyedrops (ASE) programme will only be considered if they originate from consultant ophthalmologists. All referrals will be considered by an NHSBT Specialist Therapies Consultant.
- 1.2 **Patient assessment.** Patients must normally meet the eligibility criteria specified in the document Autologous Eyedrop Serum Referral (FRM/PTI/PR/086). Patients who fall outside these criteria may still be considered for treatment on the discretion of the Consultant reviewing the referral. If the information provided by the referring ophthalmologist indicates that the patient may be a suitable candidate for treatment, the patient will be invited to attend a blood collection venue for a health assessment and serological screen.
- 1.3 **Patient acceptance.** If a patient is considered medically suitable for acceptance onto the ASE programme, a Service Level Agreement (SLA) will be issued to the organisation responsible for funding the treatment by the NHSBT National Commissioning Office (NCO). On receipt of the correctly completed SLA, the patient will be accepted onto the ASE programme.
- 1.4 **Prescription.** Requests for provision of ASE to patients accepted onto the programme must be made by the patient's ophthalmologist. Requests should be made using the form provided (by NHSBT), and directed to the NHSBT Specialist Therapies Consultant at the centre local to the patient.

1.5 Collection of blood for ASE preparation. On receipt of a request for provision of ASE, the NHSBT Specialist Therapies Consultant will confirm that the patient in question has been accepted onto the programme, and then arrange an appointment for the patient to attend a suitable donation venue. The donation (one unit of blood unless specified otherwise) will then be collected into a Dry Pack. A sample for serology testing will also be taken.

1.6 Processing. Following collection, the donation will be transferred to the Processing department at the centre local to the collection venue. It will then be processed to remove the red cell content and diluted 1.1 (w/v) with physiological saline, frozen to <-30°C and transferred to the dispensing centre.

1.7 Dispensing. Dispensing is an open process, and may only be performed by a centre in receipt of a relevant current Medicines and Healthcare Regulatory Authority (MHRA) manufacturing licence. The frozen unit will be thawed, and the diluted serum dispensed into individual dropper

bottles in a Grade A air quality environment, with a Grade B air quality background (as defined by pharmaceutical current Good Manufacturing Practice (GMP) guidelines). They will then be stored frozen at <-30°C pending release for issue.

1.8 Microbiological assessment. Each donation will be tested for mandatory markers defined in the Blood Safety and Quality Regulations. Following dispensing, one aliquot in every twenty or part thereof will be sacrificed for bacteriological and mycological testing. If any positive or indeterminate results occur, the NHSBT Specialist Therapies Consultant responsible for the patient will determine what action is necessary, consulting the patient's ophthalmologist where appropriate. Any donation issued under these circumstances may only be issued under clinical concession.

1.9 Quality release. Following completion of processing, the donation batch file will be reviewed by the manager responsible for the dispensing operations and the quality manager or deputy for the centre

where the dispensing takes place. Quality release will be dependant on satisfactory completion of all batch paperwork, acceptable environmental monitoring and microbiological results, and resolution of any quality incidents relating to the batch.

1.10 Issue. Batches may only be issued following quality release. The patient will be contacted and informed that the batch is ready for issue, and a convenient time and location for delivery agreed. The batch will be issued packaged in dry ice refrigerant using a dedicated same day courier, who will deliver the batch directly to the patient.

Part 2 – Product specification

2.1 Product description. Autologous serum, diluted 1:1 (w/v) in physiological saline solution. Aseptically packaged in 3ml (+/-10%) aliquots in glass dropper bottles and supplied frozen. Issued in batches of up to 160 aliquots depending on the volume of the original donation.

2.2 Preparation. This product is prepared from autologous blood donations. Following donation, the following processing steps are applied to the blood:

- Stored in a 4°C degree cold store for 24-72 hours to allow blood to clot
- Manual separation of serum from clot
- Centrifugation to remove any remaining red blood cells from serum
- Dilution with physiological saline (1:1, w/v)
- Dispensing into dropper bottles

2.3 Labelling and packaging. Diluted serum is dispensed into 10ml capacity amber glass dropper bottles, which are sealed with tamper evident white polyethylene caps with a foam liner. A label is applied to each bottle stating:

- The patient's name and date of birth
- Donation batch number
- Batch expiry date
- Nature of product
- Instructions for use
- Storage requirements

- Address and telephone number of the dispensing location

The bottles are packaged in white Akylux plastic trays, which are vacuum packed to prevent the individual bottles moving around in transit or storage.

2.4 Storage. Except while being processed, ASE are stored at a temperature of -30°C whilst in storage by NHSBT during transit between sites, and during transit to the patient. Following delivery to the patient, the bottles must be stored in the frozen state, in a domestic freezer or the freezer compartment of a domestic refrigerator. When stored under these conditions, the expiry date of the batch is 182 days after the date of donation.

2.5 Despatch. ASE are despatched to patients in disposable cardboard boxes insulated with polystyrene inserts. Sufficient dry ice is added to the transport box to ensure that the ASE remain frozen for a minimum of 12 hours.

Eyedroppers (to be applied to bottles following removal of the tamper proof caps) are sent in a separate disposable cardboard box. Large print instructions for document use is sent with each delivery. Delivery is by same day dedicated courier, directly from NHSBT to the patient.

Applicable Documents

MPD/PTI/PR/006 – Autologous Serum for Eyedrops

SOP/PTI/QU/023 – Concessionary Issue of Products for a Named Patient

FRM/PTI/PR/086 – Autologous Serum Eyedrops Referral

ESD/PTI/QU/001 – Guidelines for the Blood Transfusion Services in the UK, (7th Edition) (2005)

ESD/PTI/QU/002 – Rules and Guidance for Pharmaceutical Manufacturers and Distributors (7th Edition) (2007).